SCHOOL OF PHARMACY

Medication administration processes and systems – exploring effects of systems-based variation on the safety of medication administration in the UK National Health Service

Monsey Chan M^{c}Leod

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Department of Practice and Policy
UCL School of Pharmacy

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Supervisors: Professor Bryony Dean Franklin
Professor Nick Barber

Declaration

This thesis describes research conducted in the University College London School of Pharmacy between February 2009 and March 2013 under the supervision of Professor Bryony Dean Franklin and Professor Nick Barber. I, Monsey Chan M^{c}Leod, certify that the research described is original and that any parts of the work that have been conducted by collaboration are clearly indicated. I also certify that I have written all the text herein and have clearly indicated by suitable citation any part of this dissertation that has already appeared in publication.

PhD candidate's signature: …….

Date: ……

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Abstract

Medication administration errors (MAEs) in hospitals account for the majority of reported medication-related patient harm in the UK. Research suggests error-prevention strategies should focus on reducing error-producing conditions associated with systems and processes. However, medication administration is complex, and potential systems and process variations exist across the National Health Service (NHS) which present a barrier to prioritising and developing interventions to reduce error.

This thesis investigates variations in hospital medication systems and their potential effects on the safety of medication administration. It also includes a systematic review summarising hospital MAE rates and the effects of methodological variations on reported MAE rates.

An initial observational study of nurses administering medications on one ward identified several process variations and system factors that may contribute to MAEs, including potential inefficiencies and dose omissions related to medication storage. A novel meta-analysis of the literature revealed an MAE rate of 5.6% of non-intravenous doses. Dose omission was most common, of which 52-67% were because the drug was unavailable. A census of ward-based medication systems in English NHS hospitals identified the extent of inter- and intra-hospital variation, particularly in medication storage and medication safety related processes. A separate observational study documented variations among nurses in how they utilised systems, including the use of 'temporary' drug trolley alternatives. An ethnographic study of drug administration in three different hospital medication systems then revealed systems-related factors that both facilitated and hindered medication administration.

Overall, the extent of a number of variations in hospital medication systems has been described, including more subtle variations than previously reported. Many variations were associated with both positive and negative effects on the safety of medication administration, which were often affected by situational factors. This emphasises the importance of considering potential unintended consequences of sociotechnical interactions when developing and implementing systems-based interventions to reduce MAEs.

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Peer-reviewed publication

M^{c}Leod MC, Barber N, Franklin BD (2013). Methodological variations and their effects on reported medication administration error rates. BMJ Quality and Safety published online first 15 January 2013, doi:10.1136/bmjqs-2012-001330.

Conference abstract

M^{c}Leod MC, Barber N, and Franklin BD (2012). Systematic review of UK medication administration errors and methodological recommendations for future research. Abstract presented at the Royal Pharmaceutical Society conference, 8-9 September 2012, Birmingham, UK.

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Best poster award - M^{c}Leod MC, Barber N, Franklin BD (2012). Systematic review of UK medication administration errors and methodological recommendations for future research. Abstract presented at the Royal Pharmaceutical Society conference, 8-9 September 2012, Birmingham, UK.

Abbreviations

ADE	Adverse drug events
BCMA	Bar-code medication administration
CI	Confidence interval
EPMA	Electronic prescribing and medication administration
EMAR	Electronic medication administration record
IM	Intramuscular
IOM	Institute of Medicine
IQR	Inter-quartile range
IV	Intravenous
ICU	Intensive care unit
MAE	Medication administration error
MAPS	Medication administration processes and systems (MAPS study, chapter six)
MAR	Medication administration record
NHS	National Health Service
NPSA	National Patient Safety Agency
NRLS	National Reporting and Learning System
OE	Opportunity for error
OR	Odds ratio
OSD	One-stop dispensing
POD	Patients' own drugs
SC	Subcutaneous
SPO	Structure, process, outcome
TQM	Total quality management
UK	United Kingdom
US	United States

Glossary

Adverse drug event	Adverse drug events are injuries resulting from medication use (Bates et al., 1995)
Circumstance	A situation or factor that may influence an event, agent or person(s) (Runciman et al., 2009)
Contributing factor	A circumstance, action or influence which is thought to have played a part in the origin or development of an incident or to increase the risk of an incident (Runciman et al., 2009)
Error	Failure to carry out a planned action as intended or application of an intended but incorrect plan (Reason, 1990; Runciman et al., 2009)
Harm	Impairment of structure or function of the body and/or any deleterious effect arising there from. Harm includes disease, injury, suffering, disability, and death (Runciman et al., 2009)
Human factors	These are factors that can influence human behaviour and includes individual (such as perception and cognition), environmental (such as equipment design, interruptions, and distractions), and organisational characteristics (such as teamwork and culture) (Carthey & Clarke, 2009)
Incident	An event or circumstance which could have resulted, or did result in unintended or unnecessary harm to a person and/or a complaint, loss, or damage (Runciman, 2006)
Medication administration error	Any dose of medication administered (or omitted) that deviates from the patient's medication order" (Allan & Barker, 1990)

Chapter 1. Introduction

1.1 Introduction

Reducing harm from medication use is a global patient safety priority (World Health Organization, 2008; Institute of Medicine, 2007; Department of Health, 2004; Australian Commission on Safety and Quality in Health Care, 2008). In hospitals, medication errors are estimated to harm 1-2% of inpatients (Neale et al. 2001; Bates et al. 1995) and contributes to an increased length of stay of 4.6-10.3 days for each affected patient (Bates et al., 1993; Vincent et al., 2001; Pinilla et al., 2006). According to medication incident reports, medication administration errors (MAEs) account for the majority of patient harm and deaths (Cousins et al. 2007; Hicks et al. 2004), most probably because there are more 'acts' at the medication administration stage than at prescribing, dispensing, or monitoring stages, thus increasing the opportunities for error. Furthermore, MAEs are least likely to be intercepted before they reach the patient (Leape et al. 1995; Bates et al. 1995; Marino et al. 2000) which makes reducing MAEs an important priority for increasing medication safety.

While an unsafe act at the medication administration stage may precede a medication-related incident, it is widely recognised that systemic organisational and environmental factors associated with the workplace, in addition to person-specific factors, also play a role in contributing to error-producing conditions (O'Shea, 1999; Carlton & Blegen,

2006; Mcbride-Henry, 2006; Fry & Dacey, 2007; Hughes & Blegen, 2008; Brady et al., 2009; Chaudhury et al., 2009). In the United Kingdom (UK) and worldwide, key national policies and research suggest error-prevention strategies should address underlying latent error-producing conditions associated with systems and processes in hospitals (Kohn et al., 1999; Department of Health, 2000a; Australian Council for Safety and Quality in Health Care, 2002). However, systems and processes associated with medication administration are complex, and it is recognised that complexity can hinder the identification of latent error-producing conditions (Kohn et al., 1999). Thus, there is a need for further research to better understand the systems factors that contribute to MAEs to facilitate the development of effective systems-based interventions.

Furthermore, as most health care processes were not designed but have evolved (Vincent, 2011), it is suspected that system and process variations exist across the UK National Health Service (NHS). However, unlike in the United States (US) (Pedersen et al., 2012), there is no published data in the UK on the types of hospital medication systems and processes used to support medication administration. A recent survey of hospital medication procurement and distribution in Europe identified 37.5% of UK hospital pharmacies provided a unit-dose service (Frontini et al., 2012). No other sources of data on the current types of hospital medication systems or processes associated with medication administration in use in the NHS were available. Thus, the extent to which different types of systems and processes associated with medication administration exist was unknown. This presents a barrier for identifying, prioritising, and developing system-based interventions to reduce error.

A further problem associated with developing system-based interventions to reduce MAEs is the methodological approach used to evaluate interventions. It is known that

differences in definitions and MAE rate calculations exist between studies (Allan & Barker, 1990) and these can affect the reported MAE rates, which is generally the primary measure in intervention studies. However, the extent of methodological variations between studies on reported MAE rates are unknown. Furthermore, while assessing MAE rates provide one useful indicator of medication safety, measuring MAE rates alone in intervention studies do not provide information about the potential situational contributory factors that exist. Medication administration is not a single task, but a process which comprises multiple interconnected tasks, some of which contribute directly to the act of administering the dose to the patient, and some are defence barriers against MAEs. It is therefore important that multiple components of the medication administration process is measured and used to evaluate systems-based interventions.

This thesis explores variations in hospital medication administration-related processes and systems that exist across the NHS in England and investigates their potential effects on the safety of medication administration. The empirical research begins in the next chapter with a preliminary observational study that describes variations in processes and defence barriers associated with medication administration. An overall quality and safety measure is presented and the challenges of interpreting MAE rates are discussed. This is followed by a systematic literature review to summarise UK MAE studies, the methodological variations that exist between studies, and their effects on reported MAE rates in chapter three. A census of hospital medication systems in English NHS hospitals is presented in chapter four. This describes the extent of variations in a number of systems and processes used to support medication administration in hospitals, to provide a national perspective on potential priority areas for further research. Drawing on the findings in chapters two to four, a quantitative study focusing on ward-based

medication storage systems was conducted at three hospitals of one acute NHS trust to explore potential inter-hospital variation that exists and their effects on successful dose retrieval during drug rounds by nursing staff (chapter five). Variations in how nurses utilised available ward-based medication storage systems were investigated, which highlighted the complexity of other interacting systems and processes within the ward environment that potentially affected the safety of medication administration. An ethnographic study was then conducted on three wards, each located at a different hospital, using distinctly different systems, to explore the system factors that facilitate and/or hinder medication administration in more detail (chapter six). The present thesis then ends with an overall discussion summarising the main findings, limitations, together with implications for practice and recommendations for future research in this field (chapter seven).

The remainder of this chapter is a summary of the medication safety literature, with particular emphasis on MAEs, hospital medication systems and processes associated with medication administration, and theoretical concepts used to direct the research in this thesis.

1.2 Medication safety and patient harm

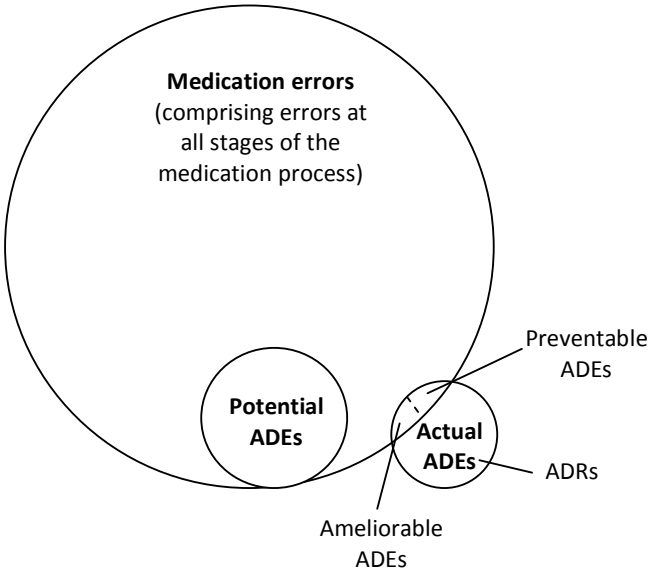
This thesis is focused on medication safety at the administration stage. However, MAEs are only part of the overall medication error picture. Thus, this section provides an overview of the scale of the medication error problem and the associated economic burden on hospitals to provide the context before focusing on MAEs in section 1.3.

1.2.1 The scale of the problem

Medication errors are a threat to patient safety. Studies published as early as the 1960s have reported on the problem of medication errors (Barker & McConnell, 1962; Hill & Wigmore, 1967). However, published research establishing medication errors as a cause of patient harm was not available until much later (Bates et al. 1995; Wilson et al. 1995; Vincent et al. 2001).

In the study by Bates et al (1995), the researchers used a combination of self-reports, informal twice weekly interviews with staff, and daily review of patient charts over a 6-month period at two large hospitals in the US to identify cases of actual and potential adverse drug events (ADEs). An ADE is defined as an injury or patient harm resulting from medication use (Bates et al. 1995), and the relationship between medication errors and ADEs is illustrated in figure 1.1 (Bates 1995; Morimoto et al. 2004).

Figure 1.1 The relationships between medication errors, actual adverse drug events (ADEs), and potential ADEs. *Actual ADEs comprises those which are preventable, ameliorable, and unpreventable (adverse drug reactions, ADRs). Adapted from Bates (1995) and Morimoto (2004).*



As depicted in figure 1.1, a preventable or ameliorable ADE is therefore harm which is the result of a medication error. Overall, the researchers identified ADEs in 6.5% of hospital inpatients and potential ADEs in 5.5% of hospital patients. Of 247 actual ADEs, 28% were judged preventable, and of the preventable ADEs, 20% were classified as life-threatening in severity, 43% as serious, and 37% as significant. Additional analysis in an accompanying paper revealed errors at the prescribing and administering stages accounted for the majority (39% and 38%, respectively) of all preventable ADEs (Leape et al., 1995).

In the study by Wilson et al (1995), the researchers reviewed over 14,000 patient case records and identified a much lower ADE rate of 1.6% of hospital inpatients in Australia. Of these, 36% were judged preventable. According to the researchers, the lower ADE rate in this study, compared with the 6.5% reported by Bates et al (1995), was probably due to the strict adverse event definition they used in comparison to the Bates et al (1995) study, thus limiting the number of included ADEs.

More recently, in the UK, a review of 840 patient records revealed a preventable ADE rate of 1% of inpatients (Neale et al., 2001). This translates to approximately 116,000 cases each year in England alone, based on the 11.6 million ordinary episodes in English hospitals between December 2011 and November 2012 (The Information Centre for Health and Social Care, 2012).

1.2.2 Economic burden of medication errors

In addition to patient harm, medication errors also contribute to the use of additional health care resource and pose a substantial financial burden on the limited health care budget. Based on studies conducted in the US, UK, and Spain, it was estimated that

preventable ADEs contributes to an increased length of hospital stay of 4.6-10.3 days for each affected patient (Bates et al., 1993; Vincent et al., 2001; Pinilla et al., 2006).

In the US, Bates et al (1997) estimated that ADEs cost USD $5.6 million and preventable ADEs cost USD $2.8 million annually (at 1993 price values) in a 700-bed teaching hospital. The costs include additional bed days, hospital charges for a range of care, and pharmacy costs. Extrapoloating these figures, each ADE was estimated by the researchers to incur a direct additional cost of USD $2,595, which almost doubled to USD $4,685 for each preventable ADE. The higher cost associated with preventable ADEs was unexpected by the researchers who attributed this to preventable ADEs being associated with more severe patient harm.

In the UK, the cost of preventable harm from medicines to the NHS has been estimated at over GBP £750 million (at 2005 price values) each year in England alone (Cousins et al., 2007). The estimate included costs from preventable hospital admissions due to medications, costs incurred from additional bed days due to adverse drug reactions (ADRs, rather than ADEs or preventable ADEs) during the hospital admission, and costs associated with litigation. The ADR rate was adjusted by a factor of 0.72 by the researchers as this was the rate of avoidable ADRs identified from a separate paper (Pirmohamed et al., 2004). This led to an avoidable ADR rate of 5.0%. However, these figures were based on definitions which suggest that patient harm due to factors other than medication errors were also included, which is perhaps not at first obvious because the term ‘preventable harm from medicines’ is often used to mean ‘harm due to medication error’ rather than ‘drug treatment that is inconsistent with present day knowledge of good medical practice’ (Pirmohamed et al., 2004). A more recent and

specific estimate of medication error costs in the UK was provided by Karnon et al (2008) (all at 2006 price values):

- GBP £0-6 for each detected medication error
- GBP £65-150 for each significant preventable ADE that does not result in increased length of stay
- GBP £810-1,232 for each serious preventable ADE
- GBP £1,232-1,760 for each severe, life-threatening or fatal preventable ADE

In addition to the above direct health care costs, the researchers also calculated the monetary value of lost health and costs associated with litigation, which ranged from GBP £16-180,000, depending on the severity of harm. Overall, Karnon et al (2008) estimated that preventable ADEs costs GBP £600,000 in annual health service treatment or GBP £17.8 million in combined annual health service treatment and monetary value of lost health, for a 400-bed hospital alone. This suggests the financial burden of medication errors on the NHS is substantially higher than that previously reported. Although the specific cost of MAEs is unknown, it is likely that reducing MAEs would result in considerable cost savings to the NHS.

1.3 Medication administration errors (MAEs)

Having established the scale of the medication error problem and the associated economic costs for health care, this section summarises the current knowledge base associated with the incidence, severity, and causes of MAEs. As the majority of MAE studies were based in the US and UK, the data presented here are generally from these two countries. This section is divided into the following subsections: (1) incidence of MAEs, (2) patient harm from MAEs, and (3) aetiology of MAEs.

1.3.1 Incidence of MAEs

Medication administration is the last stage of the medication use process before a dose reaches a patient, but errors are common. An MAE has been defined as "any dose of medication administered (or omitted) that deviates from the patient's medication order" (Allan & Barker, 1990). The incidence of MAEs in hospitals varies depending on the method of detection used (Barker & McConnell, 1962; Allan & Barker, 1990; Flynn et al., 2002). For example, a study by Flynn et al (2002) compared the MAE rates detected using three methods in 36 US hospitals: observation, chart review, and incident report review. Of the same 2,556 doses included in the study, the observation method identified an MAE rate of 11.7% of doses, chart review 0.7%, and incident report review 0.04%. This illustrates the importance of considering the method for detecting MAEs when interpreting reported MAE rates. The strengths and limitations of three main methods reported in quantitative MAE studies are summarised in table 1.1.

Table 1.1 Comparison of three methods for detecting medication administration errors (MAES) (Barker & McConnell, 1962; Allan & Barker, 1990; Flynn et al., 2002; Dean & Barber, 2001)

	Direct observation	Chart and/or medical notes review	Incident report
Strengths	• Most accurate method for detecting MAEs • Is a validated method for detecting MAEs • In the United Kingdom, MAEs are detected in real time which is a strength in that the observer can intervene to prevent patient harm but is also a limitation as it may influence the nurse's subsequent behaviour	• Relatively quick compared to direct observation • Allows review of sequential errors which may not be possible with observation unless consecutive drug rounds are observed • Data can be collected at relatively flexible times	• Can provide rich data on specific events • Within hospitals, incident reports provides regular information about some aspects of medication safety within the organisation in general • Lower cost than the other two methods
Limitations	• Time-consuming • Relatively inflexible data collection times • Costly • Training is required • Potential observer effects on nurse behaviour which may affect MAEs • Risk of observer-fatigue influencing detected MAEs • Impractical for regular monitoring purposes	• Less accurate method than observation for detecting MAEs • Does not capture errors that were not documented by individuals • Dependent on accurate documentation that reflects the true nature of what happened • Relatively time-consuming	• Least accurate method for detecting MAEs primarily due to under-reporting for the following reasons: - Does not capture errors that were not known to individuals - Actual and/or perceived lack of time to report - Psychological barriers to reporting such as fear of disciplinary action and/or perceived waste of time

Overall, research suggests observation is the most accurate method for detecting MAEs (Barker & McConnell, 1962; Allan & Barker, 1990; Flynn et al., 2002; Dean & Barber, 2001). However, observation is also associated with a number of limitations which have the potential to influence reported MAE rates (table 1.1). Mainly, observation relies on the observer to apply a consistent level of real-time objectivity in such a way that their presence and behaviour do not influence the behaviour of the observed. In practice, the effect of having an observer is difficult to quantify and will most probably vary among

different observers and the individuals being observed. Thus, adequate training and pilot observations are likely to be important precursors to increase the accuracy of MAEs detected in observational studies. Research suggests that the potential observer effect on MAE rates is low provided that the observer is discreet, non-judgemental and tactful in their approach (Dean & Barber 2001). Given that observation is the gold standard method for detecting MAEs, the incidence of MAEs in hospitals as detected by this method is next reported.

A key literature review of early MAE studies revealed observed error rates (excluding wrong time errors) between 1.6-20.6% of opportunities for error (OE) in American and Canadian hospitals (Allan & Barker, 1990). An OE was defined as "any dose given plus any dose ordered but omitted", and each dose could only be either correct or incorrect in order to prevent the error rate from exceeding 100%. The MAE rates were based on nine studies that used methods considered by the reviewers to produce valid and reliable results. However, the researchers highlighted that methodological variations were found between studies, including differences in MAE subcategory definitions which suggests that there may be some differens in inclusion/exclusion criteria that limits their comparability, and probably accounts for some of the variation in reported MAE rates. In their comprehensive literature review, Allan and Barker (1990) also summarised the advantages and disadvantages of the different methods used to detect MAE rates, and suggested a set of operational definitions for an MAE, OE, and MAE subcategories. These have since been used in several subsequent MAE studies, including some that were conducted in the UK and elsewhere (Keers et al., 2013).

In addition to individual studies of MAEs since the 1960s, there has also been several subsequent literature reviews reporting on the incidence of MAEs in hospital, each using

slightly different methods and/or present data on a specific patient cohort (Ghaleb et al., 2006; Institute of Medicine, 2007; Vincent et al., 2009; Kiekkas et al., 2011; Keers et al., 2013). In the most recent systematic literature review of 91 observational studies by Keers et al (2013), the reviewers identified a median MAE rate of 8.0% of OEs in hospital inpatients (interquartile range, IQR, range 5.1-10.9%). For intravenous (IV) OEs only, the MAE rate was much higher, at a median MAE rate of 48% (IQR 45-49%). Include wrong time errors, and the figures increase to 19.6% (IQR 8.6-28.3%), and 85.9% (IQR 81.8-89.9%), for all OEs and IV OEs only, respectively. The 91 included studies were conducted in hospitals and long-term care facilities in 16 countries, including eight in the UK. While the relevance of these figures to the UK hospital setting is unknown, the MAE rates excluding wrong time errors are comparable to the figures of 3.0-8.0% of all doses, and 49-94% of IV doses in UK hospitals reported by Vincent et al (2009).

1.3.2 Patient harm from MAEs

MAEs can cause substantial patient harm. In the UK, evaluation of 59,802 medication incidents reported to the National Reporting and Learning System (NRLS) for England and Wales between January 2005 and June 2006, revealed that MAEs were associated with 28 confirmed cases of severe harm and 24 deaths (total 52; 57% of 92 cases of severe harm and death or 0.09% of all medication incidents) (Cousins et al., 2007). The report highlighted that the numbers from incident reports were substantially lower than in research studies mainly due to under-reporting, and suggested that actual numbers of severe harm and death are likely to be much higher. This is supported by the findings from a number of observational studies of MAEs that also assessed patient harm (table 1.2).

Table 1.2 A comparison of three methods for assessing severity of patient harm in observational medication administration error studies. Data were from observational studies reported by Keers et al (2013).

	NCC MERP (1998;2001)	Dean and Barber (1999)	Folli et al (1987)
Description of method	Clinical severity of an error was classified according to nine categories (A-I), where A indicated an event that had the capacity to cause an error but an actual error did not occur, and I indicated that there was an error which contributed to patient death.	Clinical severity of an error was scored on a visual-analogue scale from 0-10, by a group of healthcare professional judges, where 0 represented no potential effect, and 10 represented an incident that would result in patient death.	Clinical severity of an error was classified into one of three categories: potentially lethal, serious, or significant.
Number of studies that used this method	6	6	5
Assessed actual or potential harm	Unknown	Potential	Actual (2 studies) Potential (3 studies)
Main findings	• 11.2% of errors were category B (error does not reach the patient) • 45-85% of errors were category C (error reaches the patient, no harm caused) • 2.7-55.1% of errors were category D (error reaches the patient, requires monitoring and/or intervention to preclude harm) • 1.1-9.1% of errors were category E (error may have contributed to or resulted in temporary harm requiring intervention) • 1.6% of errors were category F (error may have contributed to or resulted in temporary harm requiring initial or prolonged hospitalisation) • Data for categories A and G-I were not reported • One study reported no harm	**Based on mean scores (3 studies)** • Mean scores between 1.8-2.7 **Based on categorisation of mean scores (3 studies)** • 0.6-6.2% of errors were potentially severe • 57.2-60.0% of errors were moderate • 33.8-42.1% of errors were minor	• 3.3-8.9% of errors were clinically significant **Modified Folli et al (1987) criteria (2 studies):** • 10-21% of errors were potentially life-threatening • 26-42% were potentially clinically significant

NCC MERP, National Coordinating Council for Medication Error Reporting and Prevention.

Overall, table 1.2 indicates that 0.6-21% of MAEs may lead to patient harm that either resulted in prolonged hospitalisation or were potentially life-threatening. By definition, all MAEs are preventable or ameliorable, but require an understanding of the individual and systems factors that contribute to MAEs in order to address this problem.

1.3.3 Aetiology of MAEs

The aetiology of MAEs is complex. Over the past few decades, a number of studies have advanced the collective understanding of the factors that contribute to MAEs. However, before focusing on MAEs specifically, the concepts of human error in general are presented to provide context for understanding the causes of MAEs.

Humans err and systems fail

Research into the causes and factors that contribute to errors in health care has been greatly influenced by the works of Reason (1990), amongst others (Perrow, 1984; Norman, 1981; Rasmussen & Jensen, 1974), and a number of subsequent instrumental national policy documents in the UK and worldwide (Kohn et al., 1999; Department of Health, 2000a; Australian Council for Safety and Quality in Health Care, 2002). These policy documents highlighted that while humans err, systems fail; with the latter potentially having wider implications on patient safety than the former. For example, the Institute of Medicine (IOM), 'To Err is Human: Building a Safer Health System' stated:

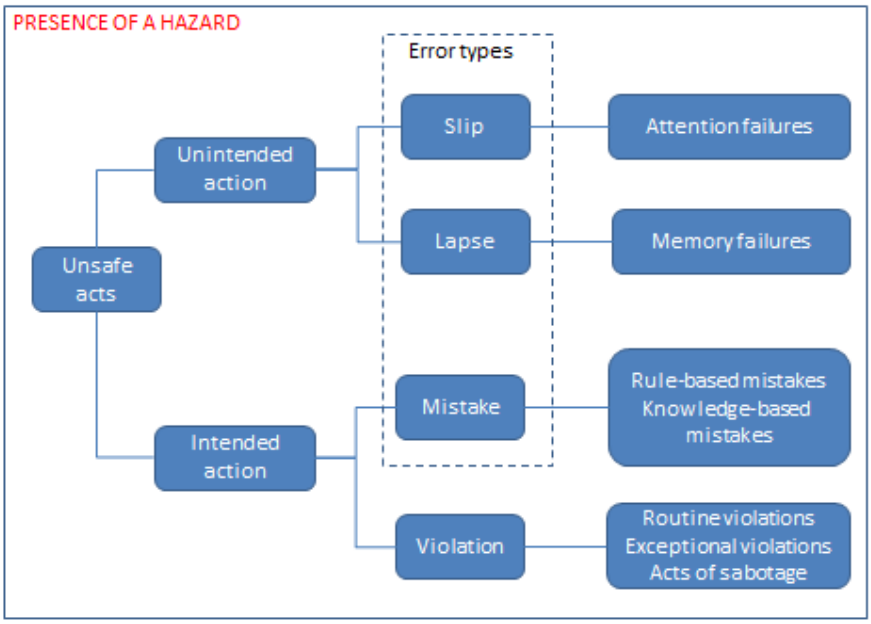
> *"[the] primary focus [of this report generally] is not on "getting rid of bad apples," or individuals with patterns of poor performance. The underlying assumption is that lasting and broad-based safety improvements in an industry can be brought about through a systems approach."*

Thus, in order to increase patient safety, including that which is associated with the use of medicines, requires an understanding of human error within the context of the systems and the work environment.

Error models of causation

Reason (2000) described two approaches in which errors may be viewed: the person approach and the systems approach. The person approach is focused on the unsafe acts of individuals at the 'sharp end', and attributes unsafe acts to an individual's lack of knowledge, skill, attentiveness and/or motivation, and includes "aberrant mental processes" such as forgetfulness, carelessness, and recklessness. An unsafe act is therefore seen as the cause of an incident and subsequent management inevitably targets human behaviour by methods such as re-training, disciplinary actions, threat of litigation, and/or wider measures such as writing another procedure. In other words, unsafe acts are errors and procedural violations; the former may be the consequence of an unintended action (such as a slip or a lapse) or an intended action (i.e. a mistake due to carrying out a 'wrong' plan), while the latter is always the result of an intentional action (figure 1.2).

Figure 1.2 Adaptation of Reason's (1990) summary of the types of unsafe acts and their psychological origins. The outer box signifies the presence of a hazard to illustrate the importance of context in defining an unsafe act i.e. it is not an unsafe act if it does not occur in a potentially hazardous situation



By comparison to the focus on unsafe acts in the person approach, human error is expected in the systems approach, even from the 'best' people in the 'best' organisations. In the systems approach, errors are considered to be primarily the consequence of more "upstream" systemic factors from the individual. These include environmental hazards associated with the equipment, the workplace, and the organisational processes such as management decisions and policies. However, this fallible human perspective does not imply that individuals are blame-free but that individual accountability should be considered within the context of the systems and organisational environment in which one works (Vincent 2011).

Person and system factors that contribute to MAEs

Based on the knowledge that contributory factors for errors are not solely due to unsafe acts, this section summarises the person and system factors that contribute to MAEs based on findings from eight literature reviews (O'Shea 1999; Armitage & Knapman 2003; Carlton & Blegen 2006; Mcbride-Henry 2006; Fry & Dacey 2007; Hughes & Blegen 2008; Brady et al., 2009; Chaudhury et al., 2009). An overview of the individual and system factors highlighted in each of the eight literature reviews are presented in table 1.3.

Table 1.3 Overview of person and system-based factors that contribute to medication administration errors (MAEs) as reported in eight literature reviews.

Factors reported to contribute to MAEs identified by the literature review authors	O'Shea (1999)	Armitage & Knapman (2003)	Carlton & Blegen (2006)	McBride-Henry (2006)	Fry & Dacey (2007)	Hughes & Blegen (2008)	Brady et al (2009)	Chaudhury et al (2009)
Mathematical skills of nurses	✓	✓		✓	✓		✓	
Nurses' knowledge of medications	✓	✓		✓	✓		✓	
Length of nurse experience and/or education level	✓	✓	✓		✓			
Length of nursing shifts	✓	✓	✓	✓		✓		
Workload, staffing levels, and/or skill mix	✓	✓	✓	✓		✓		
Nursing care and medication delivery system	✓	✓					✓	
Single-nurse drug administration	✓	✓						
Failure to adhere to policy and procedures	✓	✓		✓	✓	✓		
Distractions and interruptions	✓	✓		✓	✓	✓		
Quality of prescription and/or legibility of medication charts	✓	✓			✓		✓	
Patient acuity			✓	✓		✓		
Drug classification, unit [setting] type, complexity of medication, and/or other pharmaceutical related issues			✓	✓		✓		
Physical environment (lighting, drug preparation facilities)				✓				
Organisational culture and climate				✓		✓		
Organisational communication channels				✓		✓		
Organisational routines				✓				
Incident reporting culture				✓				
Understanding of how errors occur				✓				
Inadequate access to policies and procedures				✓			✓	
Care delivery model				✓				
Reporting medication errors				✓			✓	
Fatigue and sleep loss					✓	✓		
Similar names of drugs					✓			
Technologies						✓		
Documentation of the medication administration process						✓		
Equipment failure while administering medication						✓		
Monitoring and assessing						✓		
Medicines reconciliation							✓	
Noise								✓
Lighting								✓
Ergonomics/furniture/equipment								✓
Design/layout								✓

Shaded rows indicate person factors that contribute to MAEs.
Unshaded rows indicate systems factors that contribute to MAEs.
✓ indicate contributory factor for MAE that was specified in the literature review.

The eight literature reviews included studies conducted in hospitals in the US, Canada, UK, Australia. However, the following information were not reported: number of studies included in the review, design of studies, study settings, and methods for identifying causes or contributory factors, which limited interpretation of the literature reviews' findings. Nonetheless, the literature reviews identified a range of factors that contribute to MAEs. These illustrate the multi-factorial nature of contributory factors for MAEs and the need for more research to better understand the person and systems factors that contribute to them.

Related to understanding systems factors is the challenge of identifying them. It has been suggested that the complexity of hospital medication systems pose a challenge for detecting error-producing conditions as these latent errors are often unrecognised, but have the capacity to result in multiple active failures (Kohn et al., 1999). Thus, in order to identify latent errors, it is important to investigate the complex sociotechnical interactions within the hospital medication systems that exist, and examine their effects on the safety of medication administration.

1.4 Complexity of hospital medication systems and processes associated with medication administration

The complexity of hospital medications systems and the challenges of identifying latent error-producing conditions was alluded to earlier in this chapter. However, it has been suggested that technically it is not the system that is complex, but the interactions between processes that are complex (Perrow, 1984). This section provides an overview of complexity in relation to medication administration in hospitals, which is divided into two subsections: (1) conceptualising the hospital medication system and processes

associated with medication administration, and (2) understanding the problems of complexity.

1.4.1 Conceptualising the hospital medication system and processes associated with medication administration

Before exploring the complexity of hospital medication systems and processes associated with medication administration, it is important to establish what is meant by the following key terms: system, hospital medication system, process, and medication administration process.

The definition and description provided by the IOM offers an eloquent explanation and alludes to the complexity of studying systems (Kohn et al., 1999: p.52):

> *"A system is a set of interdependent elements [or processes] interacting to achieve a common aim. The elements may be both human and non-human (equipment, technologies, etc.). Systems can be very large and far-reaching, or they can be more localized. In health care, a system can be an integrated delivery system, a centrally owned multihospital system, or a virtual system comprised of many different partners over a wide geographic area. However, an operating room or an obstetrical unit is also a type of system. Furthermore, any element in a system probably belongs to multiple systems. For example, one operating room is part of a surgical department, which is part of a hospital, which is part of a larger health care delivery system. The variable size, scope, and membership of systems make them difficult to analyze and understand."*

Based on the above, the hospital medication system referred to in this thesis comprises all the components and processes associated with medication administration on inpatient wards, including the individuals (staff and patients) within it. This includes the prescribing system and drug distribution system which are considered part of the overall hospital medication system used to support medication administration.

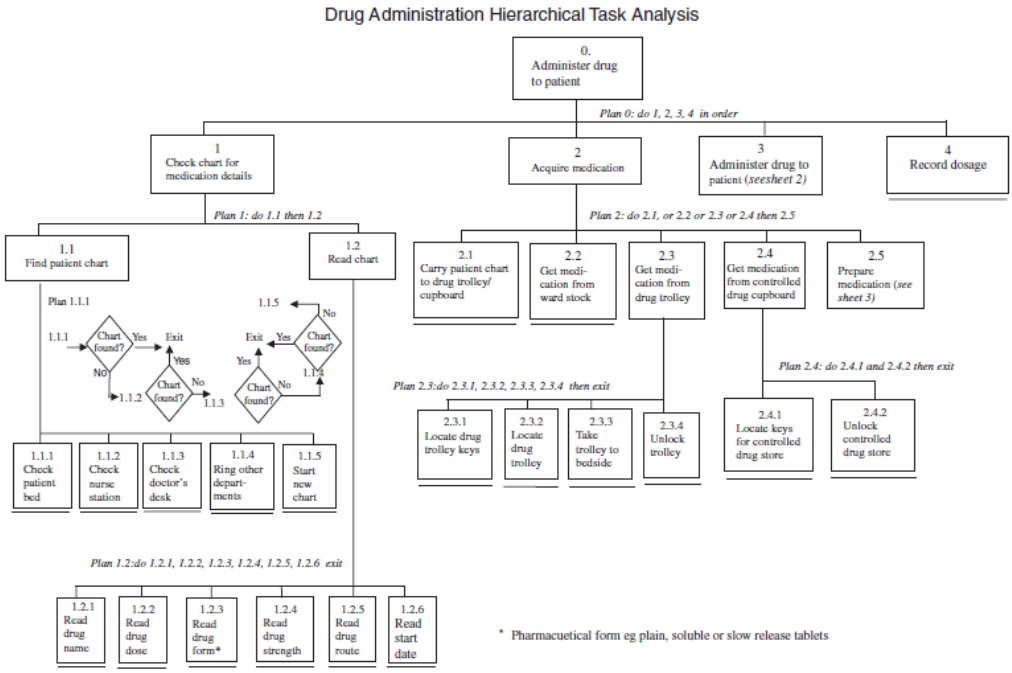
A process has been defined as follows (Nolan & Provost, 1990: p.2):

> *"A process can be defined as a set of causes and conditions that repeatedly come together to transform inputs into outcomes. The inputs might include people, materials, or information. The outcomes include products, services, behaviour, or people."*

Thus, the medication administration process comprises all (but are not exclusive to) the causes and conditions associated with identifying medication orders, storing, retrieving, preparing, and administering medications. These are required to transform the prescribed medication orders into successful administration of medication towards improving the health status or symptoms of the patients. Processes are often depicted as flow diagrams which divide the causes and conditions into sequential tasks. However, there is more than one way of conceptualising the medication administration process (Grigg et al., 2011; Lane et al., 2006). Grigg et al (2011) studied the workflow of nurses administering medications in one unit at a US hospital and identified four variations of medication administration process workflow. Lane et al (2006) applied a hierarchical task analysis of the medication administration process which divided the process into more detailed tasks. This resulted in the identification of a total of 165 tasks: from checking the chart for medication details to administering the dose to the patient (includes administering medications via all routes). Figure 1.3 shows one of

three flow diagrams from Lane et al (2006) of the medication administration process to illustrate the range of tasks required to administer a prescribed dose.

Figure 1.3 A flow diagram of the medication administration process in a UK hospital derived from a hierarchical task analysis by Lane et al (2006: p.674). *This is one of three flow diagrams by Lane et al (2006). The other two flow diagrams in the publication show a break down of tasks required to prepare, and administer the medication. Permission to reproduce this figure is covered under the publisher's guidance.*



Overall, it can be seen from the above that the medication administration process comprise a large number of components and activities. Each has the potential to fail, and each may interact in predictable and unpredictable ways that contribute to error-producing conditions for MAEs. The complexity of these interactions is next presented.

1.4.2 Understanding the problems of complexity

Much of the understanding of system complexity and the susceptibility of health care systems to patient incidents in national reports (Kohn et al., 1999; Department of Health, 2000a) have been based on human error theory by Reason (1990), which in turn was partly built on the work by Perrow (1984), from his analysis of major accidents in high risk industries. This section provides an overview of the work by Perrow (1984) on systems contributions to accidents and highlights the theoretical applications for understanding systems effects on MAEs.

Perrow (1984) suggested that the susceptibility of a system to 'accidents' is attributable to two concepts: interactiveness, and coupling. Interactiveness relates to the notions of linear and complex interactions within the system. Linear interactions are the predominant interactions within a system and are characterised by predictable, visible, and one-to-one relationships between components, for example, A is always follwed by B which is followed by C, therefore if B is not working, then C will not function, and exploration into A or other upstream components is expected to reveal the cause. By contrast, complex interactions are characterised by the opposite; the interactions involve sequences that are unfamiliar, unplanned, or unexpected, and are either not visible or are not immediately comprehensible. As highlighted earlier, hospital medication systems and the medication administration process are dependent on a large number of components. It can be seen from figure 1.3 that many of the components either are or have the potential to be involved in a complex interaction. For example, checking the drug chart may involve first searching for the drug chart; availability of the drug chart is not always predictable and the subsequent actions taken to locate the drug chart is not always consistent. This may be further complicated by

interruptions experienced during the task and subsequent actions are likely to be situation dependent and therefore unpredictable.

Coupling is a mechanical term with origins in engineering and was used by Perrow (1984) to describe the flexibility of systems in response to unpredictable changes and failures. In tightly coupled systems, there are more time-dependent processes; A is immediately followed by B and there is little waiting time in-between. The sequence is invariable (B must follow A) and the overall process is designed to reach the goal in one way, with little slack or buffer in how resources are used. Consequently, buffers and redundancies need to be designed into tightly coupled systems to support the recovery process if/when a component fails (regardless of whether the interactions are complex or linear). By contrast, loosely coupled systems can accommodate time delays, the sequence can be reordered, there are multiple methods to achieve the same goal and resources may be 'wasted' without impacting greatly on the goal. The arrangement of components in a loosely coupled system may also facilitate recovery from failure. In general, health care is considered to be a loosely coupled system (Pinelle & Gutwin, 2006), and this probably includes hospital medication systems due to the dynamic nature of the processes involved. For example, in the drug distribution system, medications can be ordered within a range of times from the pharmacy, often via one of a selection of methods. Furthermore, medications may be supplied to the ward at a range of times, and then put away in the relevant ward-based storage facilities at a time that is convenient for the nurse, rather than interrupt them. If a new medication is prescribed and is not available on the ward, the system is generally sufficiently flexible to enable nurses to obtain the drug via an alternative method to avoid a dose omission. Conversely, due to the 'looseness' of the hospital medication system, a newly prescribed

dose may not be identified and/or supplied within the required period of time, thus potentially contributing to a dose omission error.

As a potential problem, the notion of complex interactions suggest that the solution would be to simplify and make interactions more linear. However, Perrow (1984) highlights that this is not the case; in practice, complex systems can be more efficient than linear systems (for example, due to multi-functional components). Furthermore, it is not always possible to reduce complexity and produce the same 'output'. As with complex interactions, tight coupling in systems is sometimes necessary and not always seen as a problem. However, in general, systems that have tightly coupled, complex interactions are more prone to accidents than loosely coupled linear interactions as there are less opportunities and time to recover from component failure. Overall, the type of interactions and coupling within the hospital medication system and associated medication administration process are situation dependent. This creates a challenge for developing systems-based interventions because potential latent error-producing conditions may not be recognised at the time of investigation (Kohn et al., 1999). Furthermore, as most health care processes were not designed but have evolved (Vincent, 2011), it is suspected that system and process variations exist across the NHS. This presents a barrier for identifying, prioritising, and developing system-based interventions to reduce error. The concepts of variation are next discussed.

1.5 Variations in hospital medication systems and medication administration process

Variation is inherent in all things (Nolan & Provost, 1990). Exploring variations in hospital medication systems and medication administration processes may contribute to greater understanding of the interactions between individuals and the systems within which they work (sociotechnical interactions), and therefore how effective interventions may be developed to further increase medication safety. This section is divided into the following: (1) variation in the components and performance of hospital medication systems, (2) common and special causes of variation, (3) unintended and unwanted variation, and (4) system and process improvement strategies to potentially reduce MAEs.

1.5.1 Variation in the components and performance of hospital medication systems

There are several ways in which variation can be explored. In health care, a prominent type of variation is geographical variation in utilisation of resources and patient outcomes which is evident in the UK and worldwide (NHS Right Care, 2011; Public Health Wales Observatory, 2012; The Dartmouth Atlas Working Group, 2013; Health Quality and Safety Commission New Zealand, 2010). However, the variation of relevance in this thesis is at a more micro level, those associated with hospital medication systems such as availability of specific resources among institutions (Berwick 1991) and those associated with the performance of the medication administration process (for example, success rates of the same tasks between different hospitals) (Nolan & Provost, 1990). The two are connected in that variation in the components of the hospital medication systems can lead to differences in their performance. For

example, several studies have identified differences in MAE rates associated with different drug distribution systems (Means et al., 1975; Dean et al., 1995; Taxis et al., 1999), and also with different technological systems used to support medication administration (Schwarz & Brodowy, 1995; Paoletti et al., 2007; DeYoung et al., 2009; Poon et al., 2010; Franklin et al., 2007). Knowing the types of hospital medication systems-based variation that exists would therefore facilitate prioritisation of systems-based interventions to reduce MAEs.

In the US, the American Society of Health-System Pharmacists (ASHP) conducts regular national surveys of pharmacy practice in hospitals, including information on the types of hospital medication systems used to support medication administration, in addition to systems used for prescribing, transcribing, dispensing, and monitoring (Pedersen et al., 2012; 2011; 2010). From these surveys, it was estimated that, in 2011, 60% of hospitals had a centralised inpatient pharmacy drug distribution system which may have included a manual unit dose system, 40% had decentralised systems which included the use of automated dispensing cabinets and satellite pharmacies in some hospitals, 67% used electronic medication administration records (MARs), and 50% used bar-code-assisted medication administration (BCMA).

In Europe, a recent survey of hospital medication procurement and distribution, conducted by the European Association of Hospital Pharmacists, identified 37.5% of UK hospital pharmacies provided a unit-dose service (Frontini et al., 2012). However, it was unclear what was meant by a unit-dose service as no description was provided, i.e. whether it referred to the supply of single-dose medications when appropriate, or whether it was comparable to the unit-dose drug distribution system in the US which has been described as the following (ASHP, 2012: p.121):

> *"The unit dose system of medication distribution is a pharmacy-coordinated method of dispensing and controlling medications in organised health-care settings. The unit dose system may differ in form, depending on the specific needs of the organization. However, the following distinctive elements are basic to all unit dose systems: medications are contained in single unit packages; they are dispensed in as ready-to-administer form as possible; and for most medications, not more than a 24-hour supply of doses is delivered to or available at the patient-care area at any time."*

No other data on hospital medication systems used in the UK are available. This represented a gap in the knowledge of hospital medication systems used to support medication administration in the UK and a potential barrier for developing system-based interventions to reduce MAEs across the NHS. This knowledge gap is addressed later in the present thesis.

As discussed earlier, health care is a dynamic complex system that has a number of tightly and loosely coupled interactions. There is often more than one way to do most things, and the 'best' method is likely to depend on a range of situational factors. Thus, in addition to identifying variations associated with hospital medication systems, it is also important to recognise that there is inherent variation in the performance of systems and processes (Nolan & Provost, 1990). This is so that potential differences in the performance (for example, MAE rates) can be interpreted accurately.

1.5.2 Common and special causes of variation

Nolan and Provost (1990) suggest that there are two ways of interpreting variation: (1) variation that indicates good or bad performance, and (2) variation that results from common or special causes. The former is more common and is often used for assessing quality, performance, and decision-making in health care as well as other industries. However, a disadvantage of this interpretation is that the causes of variation are not considered and therefore it does not provide information about how improvements can be made. By contrast, the common and special causes of variation approach recognises that some inherent variation exist within a system (or process) and should be separated from those variations that are caused by other factors external to the system (or process), but arise in specific situations. These were named 'common causes' and 'special causes', respectively, by Deming who based this classification on the innovative work of Shewhart's statistical process control (SPC) (Berwick 1991).

According to Shewhart, a process is in a state of statistical control or 'stable' if it only has common causes that affect its outcomes (Berwick 1991). When the outcomes of a process are affected by common and special causes, the process is said to be 'unstable' i.e. the variations associated with the process are unpredictable. Deming suggested that a stable process is advantageous for a number of reasons: (1) the predictability of variations facilitates future planning, (2) costs and quality are predictable, thus (3) productivity and efficiency can be maximised, and (4) effects of system or process changes can be measured with greater speed and reliability (Berwick 1991). In the manufacturing industry, Shewhart's and Deming's work has been widely incorporated into management principles such as the Total Quality Management (TQM) techniques and Six Sigma with reported benefits on value, quality, and reliability (Bank, 1992). Subsequently, health care service providers worldwide have also sought to do the same.

The overall aims of TQM and other process improvement strategies such as Six Sigma is to eliminate unwanted variation, the rationale for reducing unintended variations in health care are next discussed.

1.5.3 Unintended and unwanted variations

In health care, it is recognised that unintended variations exist but not all imply poor quality. Variations can be beneficial when the evidence base is poor and practitioners are given autonomy to innovate, monitor and provide evidence towards identifying 'best' practice (Richards & Lilford, 2009; Hawkes, 2009). However, when unintended variations are not measured or understood, underlying problems within the system may remain uncorrected. The risk is that individuals may become used to problems associated with the system or processes, and flaw is expected, thus reducing efforts to improve, and consequently contributing to continuous waste (Berwick, 1991).

Another problem of unintended variation is that it is compounded by the complexity of the systems and processes. As Berwick (1991: p.1219) implied about hospitals:

> *"Unable to understand the underlying causes of the variation they saw, managers changed systems in response to variations that were merely random or not caused by the system in the first place, thereby adding complexity but doing no good. Systems got more and more complex, costs rose, and quality suffered."*

It has been suggested that a problem of system complexity is that it is inversely related to reliability (Berwick, 1991; Botwinick et al., 2006). Table 1.4 illustrates the relationship between the number of components in a system (or steps in a process) and the overall success rate if each component functioned properly for 95%, 99%, or 99.9% of the time.

Table 1.4 Relationship between number of components in a system or process steps and overall success rate if each component functioned properly for 95%, 99%, and 99.9% of the time. Adapted from Botwinick et al (2006)

	Probability of success for each component/step		
Number of components/steps	**0.95**	**0.99**	**0.999**
1	0.95	0.99	0.999
25	0.28	0.78	0.98
50	0.08	0.61	0.95
100	0.01	0.37	0.90

From this statistical probability perspective, the overall performance of any system (or process) can be improved if the reliability of the components is increased and/or the number of components is reduced. It has been suggested that one or both can be achieved by system-based changes (Botwinick et al., 2006). The system-based changes suggested are at the process level and is also the foundation principle for a number of systems and process improvement strategies, such as Lean and Six Sigma. These originated from the manufacturing industry and have been adopted by health care services to increase quality and efficiency (Womack et al., 2005; Westwood et al., 2007; Jones et al., 2006).

Overall, irrespective of the level at which variation is studied, the main consequence of variation is that it can interfere with interpretation and therefore subsequent actions. While the focus of this thesis is on identifying systems variations and their effects on MAEs, it is important to recognise that process variations may also exist within the system. These process variations can affect how systems variation is interpreted. Decisions are often based on whether the observed variation is considered to be within the 'norm' or indicative of something else that requires action. In health care, the price of misinterpretation include blaming individuals for system-based problems, changing a

patient's treatment when it would be better to continue (non-value processes), spending money on unnecessary equipment (wasted resources), and taking other actions when it was not needed (Nolan & Provost, 1990; Berwick, 1991). All have the potential to reduce quality and safety of care. However, the solution is not to eliminate all variations but to identify and eliminate unwanted variations that contribute to poor performance. This requires a better understanding of the variations in hospital medication systems that exist in the NHS, and is the overarching aim of the present thesis.

The next section describes the main theoretical concepts that underpinned the research approach used in this thesis.

1.6 Theoretical concepts for analysing risk and safety in hospital medication systems

In this section, a number of theoretical concepts considered for use in this thesis are described. These were principally (1) Donabedian's (1972; 2003) structure, process, outcome (SPO) model for assessing quality in health care, and (2) Reason's Swiss cheese model of accident causation (Reason 1990; 1995; Reason et al., 2001). Additional theoretical concepts that were also considered are summarised in a separate section.

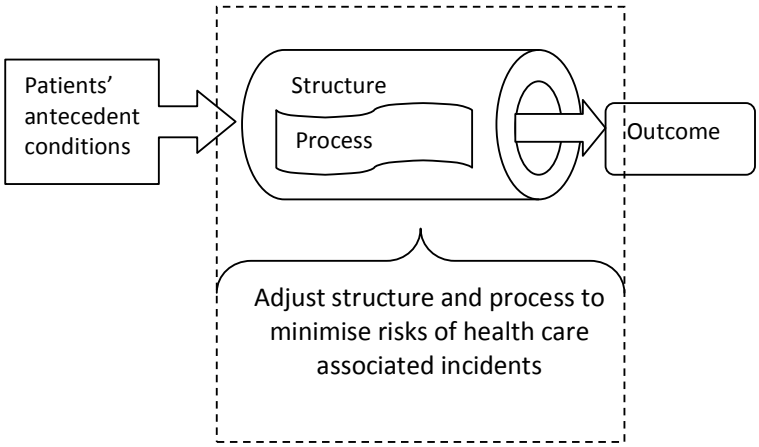
1.6.1 Structure, process, outcome

In Donabedian's (1972) influential work on assessing quality in health care, he proposed that quality can be measured using three approaches which are inextricably linked: structure, process and outcome.

- 'Structure' refers to the conditions in which care is provided and includes availability of material resources, human resources and organisational features such as training, research, supervision etc.
- 'Process' refers to the activities which are undertaken to provide the care such as diagnosis, treatment, patient education.
- 'Outcome' refers to changes in which individuals and populations can attribute to health care such as changes in health status, changes in knowledge and/or behaviour acquired by patients and/or family members that may influence future care.

While Donabedian's SPO model was originally conceptualised to assess quality, the intuitiveness of the model has allowed researchers to adapt it accordingly for use in other related areas such as organising patient safety research (Battles & Lilford, 2003), evaluation of information technology (Cornford et al., 1994), and evaluation of interventions in complex health care systems (Brown et al., 2008). For example, Battles and Lilford (2003) recognised the importance of considering the patient's antecedent conditions on the overall outcome and therefore adapted the SPO model to reflect this (figure 1.4). For studying variations in hospital medication systems, Donabedian's SPO model provides a useful approach for conceptualising variation at the process and structure levels, i.e. the study of variations associated with medication administration processes should be considered within the context of the hospital medication structure. Using this model, MAEs are a consequence of the process and not a patient outcome, but the relationship between MAEs and patient outcomes is acknowledged. Patient outcome related measures such as frequency of preventable ADEs and length of hospital stay are not specifically measured or explored in the current thesis as the focus is on understanding systems based variation.

Figure 1.4 A schematic of Donabedian's structure, process, and outcome model adapted from Battles and Lilford (2003: p.ii3) for use in patient safety. *Dotted line represents area of study in this thesis.*



1.6.2 Swiss cheese model

While Donabedian's SPO provided the analytic framework for much of the methods later described in this thesis, Reason's Swiss cheese model provided the underlying theory for using a systems approach to studying the safety of medication administration. Based on analysis of multiple major industrial accidents, Reason (1990) observed that the breakdown or failures in complex technological systems are analogous to the multi-factorial aetiology of illnesses such as cancer and cardiovascular disease. Thus, Reason (1990) suggested that latent failures in complex technological systems are similar to 'resident pathogens' in the human body. These resident pathogens may be dormant within systems and not cause any harm. However, through some external circumstances, resident pathogens may combine with 'local triggers' to weaken the system's defences and thus result in its breakdown. In his widely regarded Swiss cheese model of accident causation, Reason's resident pathogens are represented by the holes in the layers of Swiss cheese, creating gaps in the system's defences against hazards. An accident occurs when a combination of unsafe acts (active failures) combine with latent failures to allow the 'holes' to align, thus providing a clear trajectory for the hazard through the system's defences (figure 1.5). The model emphasises the importance of

targeting systemic resident pathogens to reduce accident-precipitating latent conditions. Figure 1.6 shows the Swiss cheese model in more detail as an organisational accident causation model separating organisational factors from task factors and individuals (Reason, 1995).

Figure 1.5 The "Swiss cheese" model of accident causation from Reason et al (2001: pii21). Permission to reproduce this figure has been granted by the publisher.

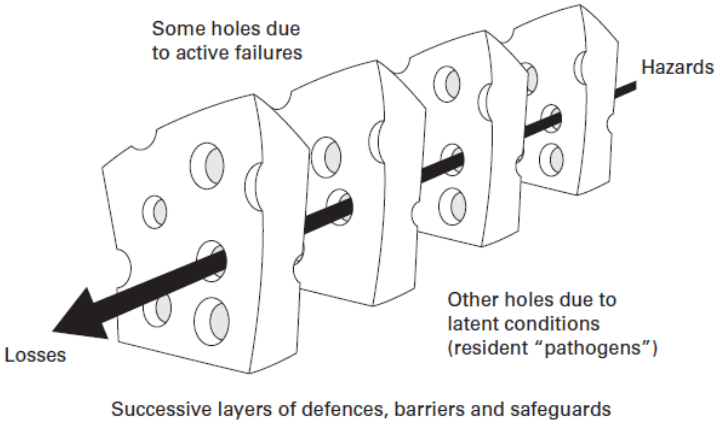
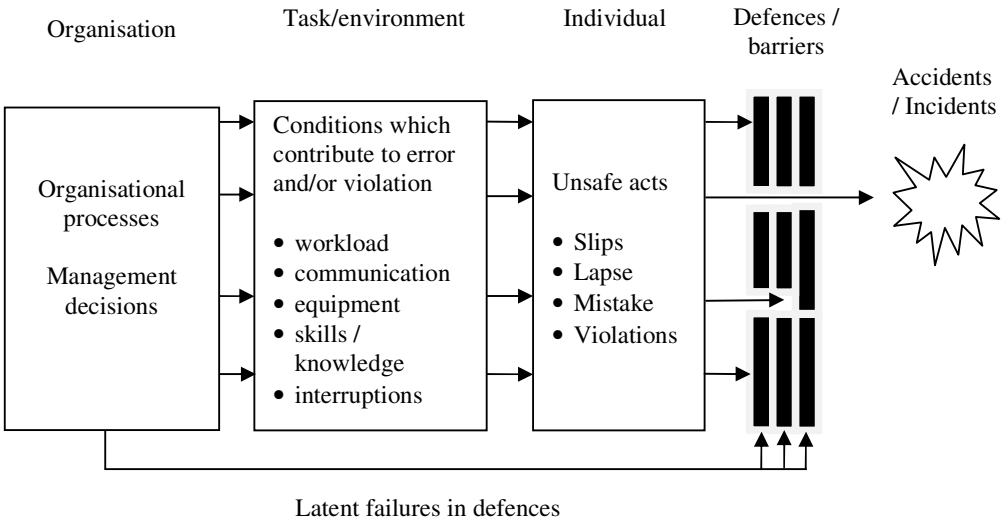


Figure 1.6 Stages of development of organisational accident adapted from Reason (1995: p83).



In the organisational accident model (figure 1.6), Reason (1995) shows the 'slices' of Swiss Cheese as being represented by four main domains: organisation, task/environment, individual, and defences/barriers. The direction of accident causality begins from left to right, and signifies the transmission of latent failures that create error-producing conditions that lead to accidents. Overall, Reason's models highlight that system factors are likely to play a major role in contributing to error-producing conditions.

1.6.3 Other theoretical concepts and frameworks

Three other theoretical concepts and frameworks were also reviewed. Table 1.5 provides a description of each of these.

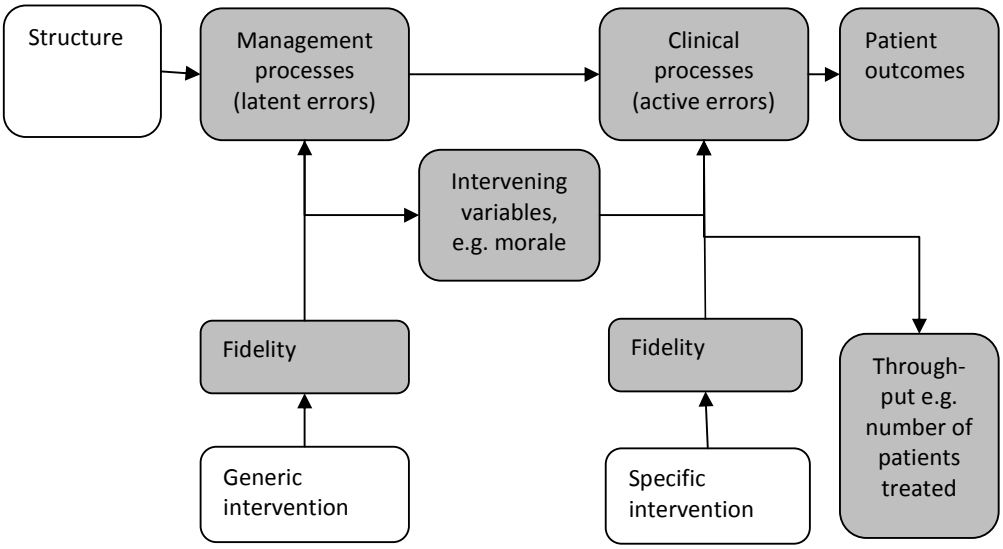
Table 1.5 Overview of three other theoretical frameworks and considerations for their use to study hospital medication system variations in this thesis.

Theoretical framework	Description	Considerations for use to study variation in hospital medication systems
The framework for evaluating information systems (Cornford et al., 1994)(table 1.6)	▪ Based on Donabedian's SPO model ▪ The framework was originally developed for evaluating the efficiency, utility and overall impact of a computer-based medical decision-aid system, and could be applied to other technological systems	Potentially useful for studying a specific system or process component but considered less useful for exploring multiple components and their variations in hospital medication systems.
Modified structure, process, outcome model for evaluating interventions in complex systems / Lilford's axiom for evaluating complex interventions (Brown et al., 2008; Lilford, 2009) (figure 1.6)	▪ Based on Donabedian's SPO model with causal links inspired by Reason's organisational accident causation model ▪ The purpose of the model is to conceptualise specific processes for developing and evaluating interventions to reduce adverse patient outcomes	As a conceptual model that combined both theoretical concepts of relevance in this thesis, Brown et al's (2009) model could have been used but the focus on interventions, and separation of management processes from clinical processes was not considered useful for this thesis.
Vincent's framework for analysing risk and safety in health care (Vincent et al., 1998) (box 1.1)	▪ Based on Reason's organisational accident causation model ▪ The purpose of the framework is to provide a comprehensive framework for analysing adverse events and identifying system and individual factors that are relevant to clinical practice ▪ Researchers also suggest that the framework can be used to develop organisational risk assessment instruments	An extensive framework that could have been used in this thesis but was considered too prescriptive for exploring variations in hospital medication systems, and the framework also included a large proportion of factors that are outside the scope of this thesis.

SPO, structure, process, outcome

Table 1.6 Cornford et al's (1994) framework for evaluating information systems			
	System functions	Human perspectives (customer, actor, owner)	Organisational context
Structure	Technical detail	Work conditions and implied requirements	Sustainability, opportunity costs, management needs, skill requirements
Process	Information processing; correct and valid	Human participation in tasks; social interaction	Altered delivery and practice
Outcome	Relevant, applicable, reliable	Quality of service, and outcomes	Effect in the world

Figure 1.7 Modified structure, process, outcome model for evaluating interventions in complex systems / Lilford's axiom for evaluating complex interventions (Brown 2009). *The shaded boxes represent the end points that could be measured in an evaluation of a patient safety intervention.*



Box 1.1 Seven health services specific factors that influence clinical practice, from Vincent et al (1998)

1. Institutional context
Economic and regulatory context

2. Organisational and management factors
Financial resources and constraints
Organisational structure
Policy standards and goals
Safety culture and priorities

3. Work environment
Staffing levels and skills mix
Workload and shift patterns
Design, availability, and maintenance of equipment
Administrative and managerial support

4. Team factors
Verbal communication
Written communication
Supervision and seeking help
Team structure

5. Individual (staff) factors
Knowledge and skills
Motivation
Physical and mental health

6. Task factors
Task design and clarity of structure
Availability and use of protocols
Availability and accuracy of test results

7. Patient characteristics
Condition (complexity and seriousness)
Language and communication
Personality and social factors

Overall, the theoretical frameworks described above provide a useful evidence-based structure for health services research, however in general, they were considered to be either too specific to a piece of technology or intervention, or too prescriptive for exploring variations relating to hospital medication systems and medication administration processes. Thus, the main theoretical frameworks that were used in this thesis were Donabedian's SPO model and Reason's organisational accident causation model.

1.7 Scope of the present thesis

Overall, this chapter has highlighted that a considerable number of patients suffer preventable harm as a direct consequence of medication errors in hospitals, and that medication errors pose a substantial financial burden on health care services. In

particular, the incidence and severity of patient harm from MAEs was described. Research suggests error-prevention strategies should focus on reducing error-producing conditions associated with systems and processes. However, as described earlier, systems and processes associated with medication administration are complex and the extent of potential variations and their effects on medication safety are unknown; these present a barrier to prioritising and developing interventions to reduce error.

Thus the overall aim of this thesis was to investigate variations in NHS hospital medication systems and their potential effects on the safety of medication administration. However, in describing the literature, it was apparent that it would not be practical to measure all the systems-based variations and their effects on the safety of medication administration. Instead, the initial approach was to consider the core tasks and defence barriers associated with medication administration as a 'whole' (chapter two). A preliminary observational study was therefore carried out to assess the overall quality and safety of medication administration and to identify potential areas for exploring systems variation. This initial approach, together with findings from addressing the gap in knowledge about MAEs (chapter three) and application of Donabedian's SPO framework, contributed to identifying a range of hospital medication system components for inclusion in a national survey (chapter four). The findings from these three areas of research then contributed to the development of two further studies; one was focused on ward-based medication storage systems and dose retrieval (chapter five), and the other was focused on investigating the sociotechnical interactions between nurses and three different types of hospital medication systems (chapter six). This thesis was therefore conducted according to the following five interlinked research questions:

1. What are the main tasks and defence barriers associated with medication administration to hospital inpatients in the NHS? (chapter two)
2. How do methodological variations between studies affect reported MAE rates in UK NHS hospitals? (chapter three)
3. What variations exist (if any) in the types of medication systems used by staff in NHS hospitals to obtain, store, and administer medication for inpatient use? (chapter four)
4. What variations exist (if any) in the types of ward-based medication storage and transport systems used by staff to retrieve medications for administration on general medical and surgical wards within one acute NHS trust? (chapter five)
5. What systems-related factors facilitate and/or hinder safe medication administration in NHS hospitals? (chapter six)

Chapter 2. Preliminary fieldwork to investigate the quality and safety of medication administration

2.1 Introduction

In chapter one, the complexity of the medication administration process was described, and the use of a systems approach to identify potential underlying latent error-producing conditions was discussed. It was decided that a preliminary observational study of the medication administration process as a whole would be useful to identify potential areas for exploring systems variation. The core tasks and defence barriers associated with medication administration, rather than MAEs alone, would be measured and used to assess the overall quality and safety of medication administration. At around the same time as this study, it was suggested that process improvement strategies such as Lean and Six Sigma, which have been used in health care to increase efficiency and reduce defects, would also reduce medication errors. However no formal studies in this area were identified at the time. Consequently, the present study was designed to form both (1) a preliminary observational study for assessing the overall quality and safety of medication administration on one general medical ward of an acute NHS hospital, and (2) a quasi-experimental study of the medicines-related aspects of a national process improvement initiative called 'The Productive Ward' (NHS Institute for

Inovation and Improvement, 2009), that was to be implemented on the same ward. Implementation of the medicines-related aspects of 'The Productive Ward' were not subsequently made on the study ward due to changes within the study hospital, and therefore no post-intervention data were collected. The study is therefore presented here as a preliminary observational study of medication administration on one general medical ward alone.

2.2 Background

Despite the recognition that MAEs are common and analysis into their causes often reveals multiple failures at the individual and organisational levels (Taxis & Barber, 2003a; Jylha et al., 2011; Nichols et al., 2008), few studies have measured a range of parameters associated with the medication administration process. Those that have, have shown that procedural failures (such as not checking a patient's identity and inaccurate documentation), and systems-based factors (such as drug not being available) are common and pose a potential problem for patient safety (Franklin et al., 2008). Furthermore, potential variation in hospital medication systems has been associated with different effects on MAEs (Means et al., 1975; Dean et al., 1995; Taxis et al., 1999; Schwarz & Brodowy, 1995; Paoletti et al., 2007; DeYoung et al., 2009; Poon et al., 2010; Franklin et al., 2007). Thus, measuring a number of parameters associated with medication administration, rather than focus solely on MAEs, may reveal potential latent underlying error-producing conditions associated with different hospital medication systems.

The tasks involved in medication administration in NHS hospitals have previously been conceptualised in a number of ways (Grigg et al., 2011; Lane et al., 2006). Grigg et al (2011) identified four variations of medication administration process workflow in one unit at a US hospital. Lane et al (2006) applied a hierarchical task analysis of the medication administration process which divided the process into more detailed tasks, and identified a total of 165 tasks

that could be associated with the medication administration process, depending on the number of problems encountered. Overall, these revealed the complexities of studying the medication administration process as a whole and the types of error that may occur. However, the reliability of carrying out each task correctly was not assessed; thus limiting the practicality of using these to identify potential areas for investigating the effects of systems variation.

Over the past few decades, process improvement initiatives from the manufacturing industry such as Lean and Six Sigma have become more widely adopted across the health care sector worldwide, including the NHS (Institute for Healthcare Improvement, 2005; Jones & Mitchell, 2006; Westwood et al., 2007). The implementation of these strategies in NHS hospitals has been associated with a wide number of benefits. These include reduced delays in processing laboratory specimens, reduced length of stay for hospital inpatients, and reduced hospital mortality in some groups of patients (Westwood et al., 2007). A recent literature review on the effects of quality improvement strategies identified reductions in infection rates and increased operating room efficiency (Nicolay et al., 2012). However, the potential effects of process change on medication safety are uncertain. It was widely assumed that process improvement initiatives would increase medication safety as a consequence of streamlining workflow, reducing system defects, and detecting mistakes early in the process (Jones et al., 2006; Womack et al., 2005). A small number of case studies have reported a reduction in medication errors (Esimai, 2006; Chan, 2004; Castle et al., 2005) but these alone are insufficient to establish potential cause and effect.

In 2008, the NHS Institute for Innovation and Improvement formally launched a process improvement toolkit called 'Releasing time to care: The Productive Ward' (NHS Institute for Inovation and Improvement, 2009). The toolkit was based on Lean principles, which aimed to guide ward staff in the use of process improvement techniques to improve ward processes and

environments (including those relating to medication administration). The overall objectives were to increase safety and efficiency on NHS hospital wards. A report from the NHS Institute for Innovation and Improvement identified a number of efficiency gains from implementation of the Productive Ward: an increase of up to 40% in the time nurses spent on direct patient care, savings of up to £30,000 was achieved from more effective use of resources, drug round times were reduced by 50%, and nurses took less physical steps to carry out tasks such as preparing IV antibiotics (NHS Institute for Inovation and Improvement, 2009). However, no direct safety measures were reported. Nonetheless, the efficiency benefits were persuasive and under the ever increasing financial and workload pressure placed on the NHS, hospitals began piloting the implementation of The Productive Ward initiative. This presented a timely opportunity to combine the preliminary observational study with an evaluation of the quality and safety of the medication administration process before and after implementation of the Productive Ward initiative.

2.3 Aim and objectives

The aim of this study was to describe and measure the reliability of a number of core tasks and defence barriers associated with medication administration, and to use these to assess the overall quality and safety of medication administration. There were four objectives:

1. To collect data on a number of core tasks and defence barriers associated with medication administration during non-IV drug rounds;
2. To combine multiple sources of data into a medication administration process 'quality filter' as an approach to derive an overall quality measure;
3. To evaluate the effect of The Productive Ward initiative on observed MAE rates using a before-and-after study design;
4. To make recommendations for future work in this area.

2.4 Methodology

Three main methodological considerations were identified and are discussed: (1) method of data collection, (2) MAE definition, denominator and subcategories, and (3) identifying the core tasks and defence barriers associated with medication administration

2.4.1 Method of data collection

The primary outcome measure of interest was the MAE rate; MAE rates can be measured using direct observation, chart review, and/or self-report. Direct observation was chosen as it is a valid and reliable method that is also widely considered to be the gold standard for collecting MAE data (Allan & Barker, 1990; Dean & Barber, 1999). This method also allowed other quality measures to be collected at the same time by the researcher (MM) who had previous experience in observing drug rounds for another study (Franklin et al., 2007). However, there was a risk that the observer may influence the individual's behaviour during the study. The largely unpredictable nature of the observer-effect on different individuals being observed is a problem that can be difficult to measure. Dean and Barber (2001) investigated the validity and reliability of observational method for studying MAEs in two wards of an acute NHS hospital. Overall, findings from Dean and Barber's (2001) study suggest MAE rates were not significantly affected when a discreet, non-judgemental, and tactful observational approach used; this corroborated findings from an earlier study by Barker and McConnell (1962). Consequently, this was the approach that was used in the current study by the observer to minimise the risk of data contamination from potential observer-effects. In addition, the researcher was introduced to all the nursing staff prior to the start of the study and piloted data collection on the same ward to enable nurses to become familiar with the presence of an observer. The researcher also made every effort to be as unobtrusive as possible and encouraged nurses to feed back about their experience of being observed.

2.4.2 MAE definition, denominator, and MAE subcategories

An MAE was defined by Allan and Barker (1990) as any dose of medication administered (or omitted) that deviates from the patient's medication order. This American hospital-based definition was used in the current study as it was specific to the medication administration process, was clear about the inclusion of dose omissions as an MAE, and has been widely used in MAE studies including in the UK, thus allowing relevant comparisons with previous research. The associated MAE subcategories by Allan and Barker (1990) are listed in table 2.1. Considerations for inclusion or exclusion of each MAE subcategory are summarised; these were largely based on a previous study that adapted Allan and Barker's MAE subcategories and were considered more operational for use in UK hospital settings (Franklin et al., 2007). The MAE subcategories were mutually exclusive; only one MAE subcategory could be associated with each dose.

In the current study, 'administration' was taken to include leaving a dose at a patient's bedside for self-administration and pharmacists' written endorsements to clarify prescribers' medication order were considered part of the medication order (Franklin et al., 2007). In circumstances where the medication order in an inpatient drug chart cross-referenced medication orders on a separate sheet, for example, a multiple resistant *Staphylococcus aureus* (MRSA) protocol, it was the separate sheet that was considered to be the medication order and not any cross-references in the drug chart.

To determine the MAE rate, the denominator used in the current study was the total number of OEs, defined by Allan and Barker (1990) as the sum of all doses given plus all doses omitted (ordered, but not given). The overall MAE rate was calculated as the number of MAEs divided by the total number of OEs, multiplied by 100 (Allan & Barker, 1990; Franklin et al., 2007).

Table 2.1 Medication administration error (MAE) subcategories used in the current study.

MAE subcategory	Description by Allan and Barker (1990) (developed for use in American hospital setting)	Inclusion, exclusion, and/or elaboration of definitions used in the current study for an MAE (based on Franklin et al 2007)
Omission	An omission error takes place when a patient has not received his or her medication by the time the next dose is due.	**Included**. A dose of medication that has not been administered by the time of the next scheduled dose (does not include doses omitted according to doctor's instructions, nurse's clinical judgement, or if patient not on ward). Omissions due to drug not being available were differentiated from other types of omissions.
Wrong dose	A wrong dose error typically occurs when the patient receives an amount of medicine that is greater than or less than the amount ordered.	**Included**. The administration of the correct drug by the correct route but in a quantity that was not that prescribed (includes administration of incorrect number of dose units, selection of the wrong strength and the measurement of an incorrect volume of an oral liquid (+/- one graduation mark from the intended volume required, or more drops than that was required).
Unordered drug	An unordered drug error occurs when a patient receives a medication for which the physician did not write an order. This includes those that result when a nurse switches medications for two patients; each patient is the victim of an unordered drug error (as well as an omission)	**Included**. The administration of a drug that was not prescribed at all for the patient concerned (classified as a wrong drug error if drug X prescribed but drug Y given instead).
Unauthorised drug	This was considered to be the same as unordered drug error	**Excluded**. Same as unordered drug error.
Wrong drug	Administration of the wrong drug was considered to an unordered drug error.	**Included**. A dose of a drug administered that is not the drug prescribed (does not include generic substitution or therapeutic substitutions in accordance with trust policy).
Wrong dosage form	Wrong dosage form errors involve the administration of a drug in a dosage form different from the one that was ordered	**Included**. The administration of the correct dose of the drug by the correct route but in a formulation that was not prescribed (includes administration of modified release when non-modified prescribed, and vice versa). Does *not* include administration of enteric coated drug instead of plain tablets if the patient states enteric coated is normally taken, or any appropriate purposeful alteration, such as substituting tablets with a soluble equivalent to help administration.
Wrong time	A wrong time error occurs when the patient does not receive his or her medication within a predefined interval.	**Excluded**. Timing of drug administration in relation to the prescribed time was measured and reported but not included as an MAE.
Wrong route	Wrong route errors occur when the correct form of drug is administered, but in the correct site on the patient's body.	**Included**. The administration of the correct drug by a route or site that was not that prescribed.
Drug deteriorated	A deteriorated drug error is reported when the physical or chemical integrity of a medication dosage form has been compromised, as with expired drugs or intravenous medications requiring refrigeration that are left out of the fridge.	**Included**. Administration of a drug that has exceeded its expiry date or a drug with its physical or chemical integrity compromised.
Wrong rate of administration	Wrong rate of administration errors can occur with infusions of intravenous fluids or liquid enteral products.	**Excluded**. The current study was focused on the administration of non-intravenous drugs.
Wrong administration technique	Wrong administration technique errors involve using an inappropriate procedure during administration of a drug. Examples include wrong inhaler technique and not wiping an injection site with alcohol.	**Excluded**. Wrong administration technique errors such as wrong inhaler technique were considered a wrong dose, and not wiping an injection site with alcohol was considered a violation of procedure rather than an error.
Wrong dose preparation	Wrong dose preparation error occurs when a product is incorrectly manipulated before administration. Examples include not shaking an oral suspension.	**Excluded**. If wrong dose preparation such as failure to shake a bottle of suspension resulted in a visible concentration gradient this is was considered a wrong dose error.
Extra dose	An extra dose error occurs when the patient receives additional dosage units to those that were authorised, such as a dose administered after the order was cancelled.	**Included**. The administration of an additional dose of a prescribed medication (includes administration of a drug more times in the day than prescribed and administration of a dose of drug after it has been crossed off the chart).
Other error	When the investigator believes that a medication error has occurred but does not fall into a predefined subcategory	**Included**.

2.4.3 Identifying the core tasks and defence barriers associated with the medication administration process

Pilot observations were conducted on the study ward to identify the core tasks and defence barriers associated with medication administration on non-IV drug rounds. Potential measures relating to the system effects were initially identified by noting common interactions between nursing staff and the medication systems used on the ward. The medication administration related measures specified in the Productive Ward toolkit were also considered for inclusion in the study: the number of MAEs and associated themes identified from medication incident reports, time taken to complete drug rounds, and number of interruptions per drug round.

To ensure the study measures were relevant and useful to staff at the study site, a group comprising four nurses of varying seniority from the study ward, the lead nurse for Medicine, the lead nurse for process improvement projects, and MM, reviewed the measures suggested in the Productive Ward toolkit and identified other potential quality measures for inclusion in the study. The quality and safety measures were based on those previously measured in other quantitative MAE studies, feedback from nursing staff on potential problematic medication administration-related areas, practicalities of data collection, and priorities for assessment locally. Additionally, two other measures were identified during the pilot observations and subsequently included in the study following discussion with the project group: (1) nurses often accessed the patient's bedside medication locker to retrieve medications but doses were not always available. It was therefore decided to also document whether or not each dose was retrieved from the bedside medication locker. (2) There was variation in the prescribed times for doses in the morning i.e. 6am and 8am but both were administered at the same time by nursing staff, and therefore the prescribed time of each dose was also documented. Evaluation of medication incident reports was excluded from the study (but continued to be reviewed according to local hospital policy) as the current study was focused on quantitative investigation of medication safety; this was discussed and agreed by the group. Both PhD

supervisors of MM provided further guidance on the measures chosen, and a final set of 10 was agreed (table 2.2).

Table 2.2 List of outcome measures included in observational study on the quality and safety of medication administration

Purpose	Outcome measure
Primary outcome measure	(i) Overall medication administration error rate
Measures of the core tasks and defence barriers for evaluating the overall quality and safety of the medication administration process	(ii) Timeliness of drug round relative to scheduled drug round time (iii) Percentage of doses given after the patient's identity was confirmed (as a match to the drug chart) prior to medication administration (iv) Percentage of doses given and/or omitted for therapeutic reasons (v) Percentage of doses that were given correctly (vi) Percentage of doses taken by the patient that were observed by the nurse (vii) Percentage of doses that were documented as administered or reason for omission recorded in the drug chart
Additional measures	(viii) Availability of medication in the patient's bedside medication locker or bedside area (ix) Number of interruptions during drug rounds (x) Duration of drug rounds

2.5 Methods

2.5.1 Study setting

The study was conducted on a 28-bed adult general medical ward of a 600-bed NHS teaching hospital. Medications were generally administered at four scheduled drug round times each day: 08:00, 12:00, 18:00, and 22:00 hours. Nurses administered medications for the patients they were looking after against medication orders prescribed on handwritten paper drug charts. Non-IV patient-specific medications were stored in individual patient bedside medication lockers, and ward stock was stored in separate stock cupboards located in a treatment room at one end of the ward. Local trust policy allowed some patient-specific medications to be kept at the bedside rather than in the bedside medication locker; these

were insulin, creams, and inhalers. Controlled drugs were stored separately in an automated drug storage unit (Pyxis MedStation™) that was accessed either via fingerprint recognition or individual user log in by two trained and registered nurses; the system was implemented in 2006 (Franklin et al., 2010).

The ward operated a patients' own drugs (PODs) and one-stop dispensing (OSD) scheme, as endorsed nationally (Audit Commission, 2001; Department of Health, 2000b). In the PODs scheme, patients were encouraged to bring their medicines into hospital to facilitate accurate medicines reconciliation, minimise the risk of missed doses due to medication not being available, and thus reduce waste, in addition to increasing safety. The OSD scheme involved pharmacy staff dispensing 28-day inpatient-specific supplies labelled with instructions on how to take the medicine; these were intended for both inpatient administration and given to patients at discharge thus minimising repeat dispensing, and reducing waiting time for medication supplies. Medicines that were unlikely to be continued post discharge were not dispensed as OSD; instead ward stock or non-OSD inpatient supplies (medications labelled without directions) were used. During pharmacy opening hours, nurses ordered medications via the ward pharmacist and/or by going to the pharmacy dispensary. Outside pharmacy opening hours, an emergency on-call resident pharmacist was available who could be contacted for obtaining medicines if necessary.

2.5.2 Data collection

Non-IV drug rounds were observed by MM and data recorded on pre-piloted data collection forms (appendix 1). Nurses were informed of the study objectives during staff meetings and given opportunities to ask questions about the study. MM arrived approximately 1-2 hours prior to the drug round time as pilot work revealed nurses sometimes started the drug round up to two hours early. Verbal consent from each nurse was obtained prior to the start of any

observations. In general, the ward was divided into four sections during the 08:00, 12:00 and 18:00 hour drug rounds and two sections for the 22:00 drug round. As the nurse looking after each section often started their respective drug rounds at similar times, only one section of the ward was observed at any one scheduled drug round time. Observations were organised to ensure all four scheduled drug round times were observed on all seven days of the week over 20 days; these were approximately equally distributed across all sections of the ward.

All MAEs observed, defined as "*any dose of medication administered (or omitted) that deviates from the patient's medication order*" (Allan & Barker, 1990), were documented; each were categorised according to table 2.1. Consistent with the approach used in previous observational MAE studies, MM intervened whenever there was a risk that the patient would be harmed as a result of the MAE. Errors prevented by MM or the patient were included as MAEs, those prevented by other health care professionals were not. The clinical appropriateness of the prescription was not assessed. All regular, "when required" and "once only" non-IV medication orders that were due on the scheduled drug round observed were included. Doses given in between the four daily scheduled drug rounds were excluded; controlled drugs were therefore also excluded as these were generally prepared between drug rounds when two nurses were available. In addition, any dose that could not be observed, for example, rectal administrations were also excluded. Medical gases, dietary supplements, and thromboembolic deterrent stockings were excluded from the study.

Confirmation of a patient's identity was recorded if the nurse visibly checked the patient's identity band against the details on the drug chart and/or asked the patient to confirm their name and date or birth prior to drug administration. Availability of the medication at the patient's bedside was taken to include successful dose retrieval from the patient's bedside medication locker, and/or any area around the bedside. A dose taken by a patient was considered observed by the nurse if the nurse remained at the patient's bedside while the

patient took the dose and/or if the dose was administered directly to the patient by the nurse. Five types of administration documentation were recorded: (1) dose was administered and signed for, (2) dose was administered but not signed for, (3) dose was not administered and a reason documented, (4) dose was not administered but signed to suggest it was administered, and (5) dose not administered and not signed.

Timing of each drug round observed started when the nurse picked up the first drug chart for medication administration and stopped after the last dose was administered or drug administration was documented (whichever was the last task). The prescribed time for each dose observed was also recorded.

The number of interruptions during each drug round observed was recorded. An interruption was defined as any action(s) from a person (other than the patient to whom medication is being administered) that prevents the nurse from continuing with the drug round. For example, an interruption included the nurse being called away to answer a telephone call, being asked by a different patient to do something which takes the nurse's attention away from the task of medication administration. An interruption did not include any interaction between the nurse and the patient, to whom medication was being administered, for example, talking to the patient, answering questions from the patient.

2.5.3 Sample size

A sample size calculation was made on the assumption that an intervention would be made. Based on a normal approximation to the binomial distribution, a sample of 634 observed dose administrations before and after an intervention was required to provide a power of 80% to detect a reduction in MAEs from 7% (Franklin et al., 2007) to 3.5% based on a two-sided test with an α of 0.05. The reported baseline MAE rate from Franklin et al (2007) was used for the

following reasons: (1) many of the methods used in the current study were adapted from Franklin et al (2007), (2) the study was conducted at the same hospital and thus the MAE rate identified might be expected to be comparable, and (3) this was the most recent UK study of MAEs identified at the time. Data were collected until this sample was achieved.

2.5.4 Data analysis

All data were analysed using descriptive statistics. In addition, a cumulative quality filter of six medication administration related measures was constructed which comprised: (1) timeliness, calculated as the percentage of doses administered on a drug round that started and finished within each of 1, 1.5, and 2 hours of scheduled round time, (2) percentage of doses where the patient's identity was checked prior to administration, (3) percentage of doses that were given and/or omitted for a therapeutic reason, (4) percentage of doses given that were administered correctly, (5) percentage of doses where the nurse observed patient taking the medication, and (6) percentage of doses that were correctly documented. The cumulative quality filter was produced by adapting the approach used by (Garfield et al., 2009). This involved identifying the key medication process steps, superimposing the compliance rate at each process step and then calculating the cumulative compliance rate by aggregating the compliance rate at each step with the preceding compliance rates; all compliance rates for the quality filter were calculated using the same denominator. In the present study, the reliability of each of the six tasks was determined and then combined in a stepwise manner to produce an overall percentage of 'compliance with standard good practice'. Additionally, an overall MAE rate was calculated using the total number of MAEs identified divided by the total number of opportunities for error, multiplied by 100. The timing of actual drug round start times was also compared with prescribed times of observed doses.

2.5.5 Ethical considerations

Research ethics approval was not required as the local ethics committee considered this study to be service evaluation.

2.6 Results

Overall, twenty-nine drug rounds were observed over 20 days between May and June 2009. A total of 650 OEs were observed, involving eighty-five different drugs. Characteristics of the drug rounds observed are summarised in table 2.3. Since no medication-related process improvements were subsequently implemented, no follow-up data were collected. The results are therefore 'pre-intervention' data only.

Table 2.3 Characteristics of drug rounds observed.

	08:00	12:00	18:00	22:00
Number of drug rounds observed	9	6	6	8
Mean number of patients per drug round (range)	6 (3 to 8)	4 (2 to 6)	6 (4 to 6)	10 (6 to 11)
Mean number of OEs per drug round (95% CI)	35 (28 to 41)	8 (5 to 10)	14 (10 to 19)	26 (21 to 31)

CI, confidence interval; OE, opportunities for error

2.6.1 Quality filter for the medication administration process

Overall, 15.4% of OEs (approximately one in seven doses) was administered according to the quality measures of standard good practice (figure 2.1); the overall percentage was based on defining timeliness as dose administrations on drug rounds that started within 1 hour of the prescribed time, and increased when the timeframe was raised to 1.5 hours, and 2 hours. The results for each of the six measures of quality were as follows:

(1) **Timeliness** in relation to prescribed time – see figure 2.1

(2) **Patient identity check** – 37.5% of doses where the patient's identity was checked prior to administration

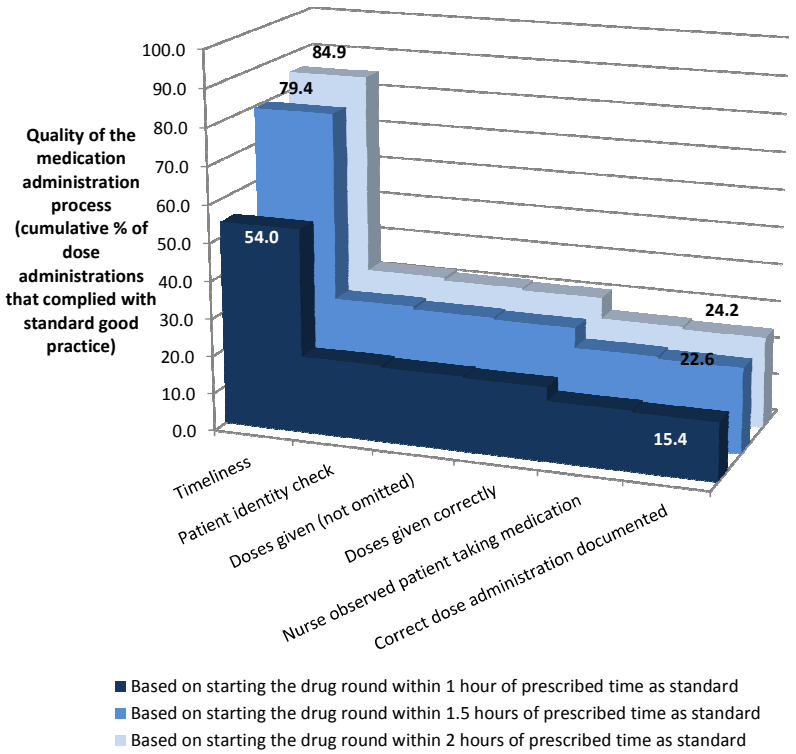
(3) **Doses given (not omitted)** – 97.4% of doses were given (excludes dose omissions due to therapeutic reasons)

(4) **Doses given correctly** – Of the doses that were given (and not omitted for therapeutic reasons), 98.3% were given correctly

(5) **Nurse observed patient taking medication** – 81.6% of doses administered were taken by the patient and observed by the nurse

(6) **Correct dose administration documentation** – 97.2% of doses were correctly documented to indicate whether or not the dose had been administered or omitted

Figure 2.1 Quality filter of the medication administration process comprising six components of standard good practice



2.6.2 Quality and safety measures

Of 591 doses administered, 524 (88.7%; 95% CI 86.1-91.2%) were available and retrieved from the patient's bedside medication locker or bedside area. Table 2.4 summarises medication availability during different drug round times and includes a comparison of interruptions and duration. In all, 25 (86%) drug rounds had at least one interruption with a median of three interruptions per drug round hour (range 0 to 9).

Table 2.4 Comparison of drug round duration, interruptions, and availability of medications in the patient's bedside medication locker or bedside area at different scheduled drug round times.

	Scheduled drug round times			
	08:00	**12:00**	**18:00**	**22:00**
Mean duration (95% CI) minutes per drug round	75 (59 to 92)	37 (16 to 57)	37 (30 to 43)	76 (54 to 99)
Median number of doses attempted per drug round hour (range)	32 (17-54)	14 (10-51)	30 (11-68)	17 (13-43)
Interruptions				
Median number of interruptions per drug round (range)	3 (0 to 11)	1 (0 to 6)	1.5 (0 to 3)	5 (1 to 8)
Median number of interruptions per drug round hour (range)	4 (0-7)	3 (0-5)	3 (0-4)	3 (1-9)
Availability of doses in the patient's bedside medication locker or bedside area				
Median number of doses available in the patient's bedside medication locker or bedside area (range)	33 (17 to 40)	6 (3 to 11)	9 (5 to 20)	23 (14 to 35)
Median % of OEs that were available in the patient's bedside medication locker or bedside area (range)	88 (74-100)	85 (60-92)	74 (50-87)	88 (67-95)

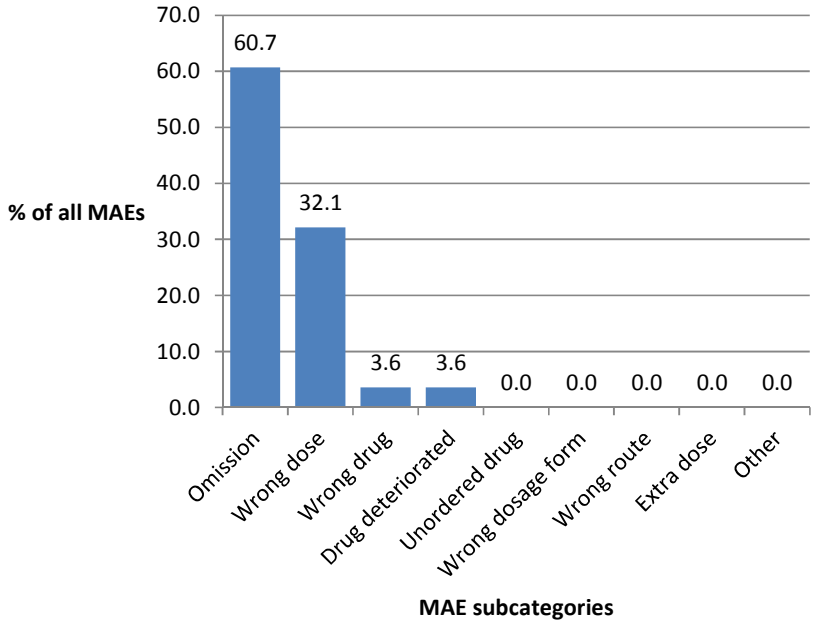
CI, confidence interval; OE, opportunity for error

2.6.3 MAEs

There were 28 MAEs in 650 OEs, giving an overall MAE rate of 4.3% (95% CI 2.7-5.9%). The majority (17; 60.7%) of MAEs identified were due to dose omissions, of which 5 (29.4%) were due to drug not being available. Figure 2.2 shows a breakdown of MAEs by subcategory. Five

interventions were made by the researcher; these are described in box 2.1. Exploratory sub-analysis of associations between MAEs and time of day suggested that there may have been more MAEs during the 18:00 drug round than at 08:00 (table 2.5).

Figure 2.2 Frequency of MAE subcategories identified as a percentage of all 28 medication administration errors (MAEs) detected.



Box 2.1. Summary of five medication administration errors that resulted in an intervention by the observer.

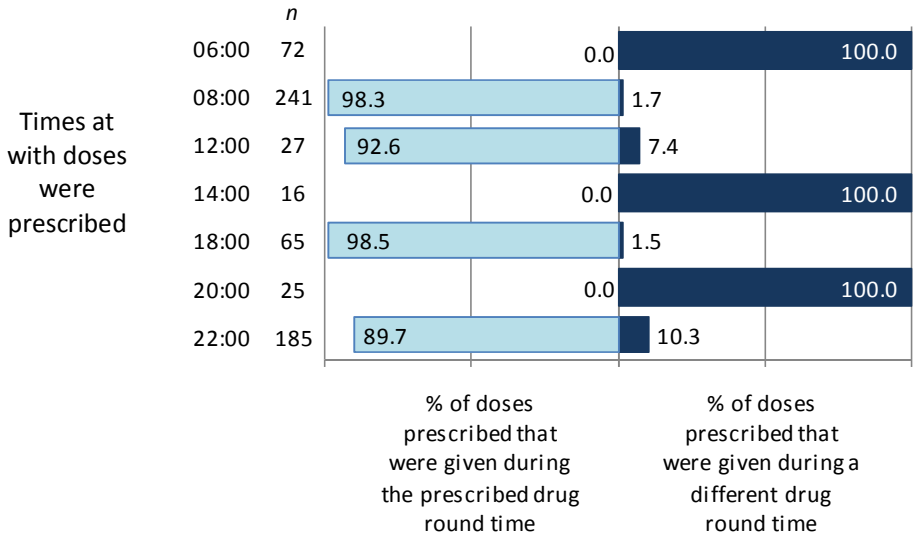
- Gliclazide 40mg was prescribed, nurse was about to give a whole 80mg tablet instead of half a tablet
- Clotrimazole cream was prescribed, nurse was about to administer chloramphenicol eye drops (the latter was no longer prescribed, patient had an old bottle in bedside medication locker and the nurse had intended to administer a dose against the clotrimazole cream)
- Co-beneldopa 125mg was prescribed, available strengths in the patient's bedside medication locker were 62.5 (12.5/50) and 125 (25/100), nurse was about to administer one tablet of the 62.5 strength.
- Sando K (potassium chloride) three tablets stat was prescribed, the dose was not administered and chart not signed, researcher waited until nurse confirmed drug round was complete and then intervened
- Co-beneldopa 125mg was prescribed, drug not administered and not signed, researcher intervened when nurse moved on to the next patient

Table 2.5 Exploratory comparison of medication administration error (MAE) rates at scheduled drug round times			
Drug round	**OE**	**MAE**	**MAE rate (95% CI)**
08:00	311	5	1.6% (0.2 to 3.0)
12:00	46	1	2.2% (0 to 6.5)
18:00	85	8	10.4% (4.1 to 16.6)
22:00	208	14	7.2% (3.8 to 10.6)
CI, confidence interval; OE, opportunity for error			

2.6.4 Safety relating to timeliness

In all, medications were prescribed at seven different scheduled times (rather than the four scheduled drug round times). A total of 518 (82%) doses administered were prescribed for the same time as a scheduled drug round time; of these, 492 (95%) were administered on the scheduled drug round time prescribed, the remainder were administered at a separate drug round (figure 2.3).

Figure 2.3 Percentage of doses that were prescribed and administered during the same drug round time (total 631 doses administered). *n represent number of doses prescribed for each of seven different times.*



Separately, sub-analysis of time interval between the start times of 18 consecutive drug rounds showed variation in duration between drug rounds with some less than 4 hours apart and some over 11 hours apart (table 2.6). The same section of the ward was not always observed on consecutive drug rounds; however nurses generally started and finished concurrent drug rounds at similar times. A total of 137 (21%) of all OEs were for medications that were prescribed for administration four times a day.

Table 2.6 Time interval between start times of 18 consecutive drug rounds observed. The same section of the ward was not always observed on consecutive drug rounds; however nurses generally started and finished drug rounds at similar times.

Consecutive drug rounds observed	Number observed	Time interval (hours) between the start times of consecutive drug rounds observed		
		Mean	Min	Max
08:00 then 12:00	5	3.9	3.4	4.9
12:00 then 18:00	3	5.2	5.2	5.3
18:00 then 22:00	5	3.4	3.0	3.7
22:00 then 08:00	5	11.4	11.3	11.7

2.6.5 Safety relating to documentation of administration

Nurses administered the dose and signed the drug chart for 585 (90.0%) of 650 OEs; 47 (7.2%) doses were not administered and the reason was documented. The remaining 18 (2.8%) cases of incorrect documentation are summarised in table 2.7. Of these, 11 (61.1%) were not administered nor signed by the nurse, and 7 (38.9%) were signed by the nurse as "drug not available".

Table 2.7 Types of inappropriate documentation or omission of administration documentation.

Type of inappropriate documentation or omission	Scheduled drug round times				Total (%)
	08:00	12:00	18:00	22:00	
Dose was administered but not signed	2	2	2	1	7 (38.9)
Dose was not administered but signed	0	0	0	0	0
Dose was not administered and not signed	0	0	4	7	11 (61.1)
Total	2	2	6	8	18 (100)

2.7 Discussion

2.7.1 Main findings

An MAE rate of 4.3% for non-IV doses was identified. Overall findings indicate the processes of administering apparently straightforward non-IV doses appear to have a number failings in addition to MAEs that potentially lower their quality and safety; some were related to individual procedural violations (such as not confirming the patient's identity prior to administration and inaccurate administration documentation) while others indicate potentially more organisational-related problems (such as unavailability of medication and less than four hour intervals between consecutive drug rounds). In the current study, six quality and safety measures were combined to reveal that only 11.8-25.5% of doses observed complied with the six nominal standards of good practice for medication administration at the study site. 'Failures' were apparent for each of these six quality and safety measures; two variables associated with the lowest 'quality' were timeliness of drug rounds and confirming the patient's identity prior to administration. Findings relating to the following are next discussed in detail: (1) MAEs and considerations for use as a quality and safety measure, (2) discrepancies between prescribed time, scheduled drug round time, and actual drug round times – an underlying latent failure? (3) patient identity check – an inadequately used defence barrier, and (4) medication retrieval and storage.

2.7.2 MAEs and considerations for use as a quality and safety measure

The primary measure of quality and safety in the current study was the MAE rate, which was 4.3%; or approximately one MAE in every 25 doses. This MAE rate is lower than the 7.0% for non-IV doses previously reported by Franklin et al (2007) that was used to derive the sample size, but consistent with MAE rates of 3.0-8.0% for non-IV doses reported in other similar observational studies (Dean et al., 1995; Ho et al., 1997; Cavell & Hughes, 1997; Taxis et al., 1999). Exploratory sub-analysis of MAE rates at different times of day suggested that more

MAEs occurred during the 18:00 and 22:00 drug rounds than at 08:00. This is different from other studies which have found the 12:00 drug round to be associated with the most MAEs (Franklin et al., 2008; Ho et al., 1997), and may reflect differences in inherent common causes of variation (chapter one) associated with the specific ward setting. For example, Ho et al (1997) found higher MAE rates during the first 48 hours of admission and in the first 48 hours of prescribing on an acute admissions ward; the patient turnover on that ward was much higher than on the current study ward of general medical patients and therefore the potential effect of patient admissions may not have been a factor in the current study. Franklin et al (2008) attributed a higher MAE rate at midday to a potentially greater number of interruptions and activity on the ward. While the study by Franklin et al (2008) was not designed to assess the effects of interruptions on MAEs, a separate study was identified that investigated the relationship between interruptions and MAEs. Westbrook et al (2010) observed a total of 4,271 drug administrations by nurses at two major teaching hospitals in Australia. The researchers identified a correlation between the number of interruptions and errors; each interruption was associated with a 12.1% increase in procedural failures and a 12.7% increase in clinical MAEs (Westbrook et al., 2010). However, findings from the present study suggest there were more interruptions at 08:00 and 22:00 than at other times (although not statistically significant), however, the MAE rate was lowest at 08:00 (1.6% of OEs; 95% CI 0.2-3.0%) and highest at 18:00 (10.4%; 95% CI 4.1-16.6). Overall, these findings suggest other factors, in addition to or other than interruptions, played a more prominent role in affecting MAE rates in the present study. Based on analysis of medication administration documentation, more doses were inaccurately documented during 18:00 and 22:00 than at other times (although statistical significance was not explored due to small sample); these were mainly due to doses that were omitted and not signed, suggesting potential oversight to be more problematic later in the day. Overall, findings from this study suggest that analysis and interpretation of MAE rates alone may not be sufficient to explain the potential causes. Concomitant data collection of other parameters associated with the medication

administration provides an enhanced understanding of the safety of medication administration process.

2.7.3 Discrepancies between prescribed time, scheduled drug round time, and actual drug round times – an underlying latent failure?

Observations revealed that 82% of doses administered were prescribed for the same time as a scheduled drug round time; this meant that 18% of doses administered were not planned to be given around the prescribed time. This was because doses were also prescribed regularly for 06:00, 14:00, and 20:00. The mismatch between the prescribed times and the scheduled drug round times present a potential technical problem in the measurement of quality and safety. Timeliness is generally measured against the prescribed time, however in practice, timeliness is usually only relevant for a relatively small group of drugs: for example, time-critical medicines such as anti-Parkinsonian drugs, and time-interval critical medicines such as those that require administration four or more times a day. Thus, while some doses prescribed for 06:00 may be administered at the 08:00 drug round, these are not always a problem and do not infer 'lower' quality or safety. However, for time-interval critical doses, timing of administration may be more problematic. In particular, findings from the current study suggest that some consecutive drug rounds were started less than 4 hours apart, and others over 11 hours apart; these could potentially result in sub-optimal drug profile levels of time-interval critical drugs. Consequently, it may be more useful to assess timeliness for time-critical and time-interval critical medicines rather than for all.

Unfortunately, it was rarely clear when timeliness was critical on the drug chart without knowledge of the medications prescribed; such information was generally not provided. Instead, much of the responsibility to ensure that time-critical doses are recognised and administered on time seems to be burdened on nursing staff; this is likely to require a

combination of medicines knowledge and memory to identify and keep track of such doses for all patients. This highlights a potential underlying limitation of the medication prescribing and administration system; which may also be considered a latent failure.

2.7.4 Patient identity check – an inadequately used defence barrier

Of all the measures recorded in the current study, the largest deviation from standard good practice was the percentage of doses given after the patient's identity was confirmed by the nurse (37.5% of OEs). This figure is higher than 17.4% of doses previously reported in a similar observational study (Franklin et al., 2007). One possible reason for higher compliance may be related to the presence of an observer. In the current study, the observer noticed that some newly observed nurses (i.e. not observed during the piloting stage) tended to check the first few patients' identity during the drug round but would then revert to addressing subsequent patients by their first name as the drug round progressed. Although the absence of a check may not lead to patient harm, 66% non-compliance is high and evidence from other research suggests this preventable risk to patients has yet to be resolved (Franklin et al., 2007; Koppel et al., 2008). Furthermore, it has been suggested that not checking a patient's identity prior to administration may be indicative of non-compliance to other procedures that also increase the risk of error (Westbrook et al., 2011). In the UK, in 2007, there were 2,781 incidents of mismatch between patient and medicine reported to the NHS NRLS; of these, two patients suffered severe harm and there was one patient death (Cousins et al., 2007). These incidents may have been avoided if the patient's identity was confirmed as a match to their medication order prior to drug administration.

2.7.5 Medication retrieval and storage

The findings from the current study suggests that despite the use of PODs and OSD stored in patient bedside medication lockers, 11.3% of doses administered were not available at the

patient's bedside. Having the right medications at the patient's bedside should help to minimise time spent looking for medication and it was inferred that measuring the percentage of doses that were unavailable at the patient's bedside provides an indication of the amount of "excess travel" nurses make during drug rounds. However, from observations, a number of nurses would routinely store medications in their pockets in anticipation that a medication will not be available at the patient's bedside, for example, syringes of enoxaparin and paracetamol tablets. This suggests that potential problems or inefficiencies associated with medication storage exist and are perhaps common. While experienced nurses may take preventative actions to manage the potential inefficiency, others may take more time to retrieve medications during drug rounds unless the underlying potential medication storage inefficiency is addressed.

2.7.6 Strengths and limitations

A limitation of the current study was that the process improvement initiative was not implemented on the study ward and therefore the potential effects on the quality and safety of the medication process could not be examined. However, a strength of the current study was the inclusion of a range of quality and safety measures to study the medication administration process. Another strength was the use of observation; this allowed MAEs to be recorded more accurately and consistently, and also provided the context that facilitated data analysis. In general, nurses did not seem to mind being observed and no obvious change in behaviour was identified other than those associated with confirming patient's identity. A limitation was that a number of other potential confounding factors that may affect the quality of the medication administration process were not collected: nurse experience, number of admissions and number of new medication orders. It would be useful to know what the extent (if any) of these factors had on the MAE rate as there is the possibility that some of the MAEs may be restricted to a small number of patients, staff or medication order. Furthermore,

severity assessments of the MAEs were not conducted. It would have provided an additional dimension to the potential impact of the MAE rate and therefore a stronger safety indicator of the quality of the medication administration process. Finally, the current study was based on one ward, by one observer which limits the generalisability of the study.

2.7.7 Implications for practice

In the current study, identifying time-critical and time-interval critical doses was found to be a potential problem; EPMA systems potentially offer an opportunity to resolve this by employing a design function that alert nurses to time-critical and time-interval critical doses; thus minimising the need for individuals to rely on their memory. Additionally, use of bar-code technology has been associated with a greater compliance in confirming a patient's identity prior to administration in a UK hospital (Franklin et al., 2007). However, care should be taken when designing, choosing and/or implementing technologies in health care; as discovered from research of technological workarounds (Koppel et al., 2008), implementation of electronic systems may not resolve the problem entirely, and potentially create new problems.

2.7.8 Future research

Several definitions for MAEs and associated subcategories have been reported in past studies in the UK, the US, and other countries. While it was outside the scope of the current study to review all the definitions used, it was soon realised that the implications of such diverse terminology posed a potential barrier for interpreting and comparing research in the area; a systematic literature review was therefore carried out separately to the current study and is described in chapter three of this thesis.

In addition, the potential problem of inefficient medication storage also warrants further research. Findings from the current study suggest nurses took preventative action to avoid

having to travel back and forth between the patient and the stock cupboard for some drugs. While some preventative practices may have been considered risky (unused medicines may be left in the pocket and expire, nurses may accidently take medicines home), these practices may have potentially increased drug round efficiency and also reduced the number of interruptions to nurses during drug rounds. Research has found 22% of interruptions occurred when nurses were in the medication storage room (Potter et al., 2005). As highlighted earlier, Westbrook et al (2010) identified an association between the number of interruptions and errors. Furthermore, the researchers also found the risk of a major error doubled (4.7% of errors) when there were four interruptions than when there were no interruptions (2.3% of errors). Thus, by taking preventative action to minimise excess travel and interruptions, it is possible that the risk of MAEs may also be reduced; however, this inference is outside the scope of the present study.

While the problem of medication not being available may be partly because the ward no longer used conventional drug trolleys during drug rounds, previous research have found that doses are not always available from drug trolleys even when they are used (Dean et al., 1995; Taxis et al., 1999). Thus potentially more efficient methods of storing medications for timely retrieval and administration may be required. However, the problem (and thus the solution) of medication storage is likely to affect many parts of the NHS. Consequently, a more systems-based approach to understanding this is required. First however, we need to identify what current types of hospital medication systems exist, including ward-based medication storage facilities. A national survey of hospital medication systems in English hospitals is presented in chapter four.

2.8 Conclusion

Medication administration is a complex process, and there were failures at each step of the process measured in this study, including two which were also defence barriers against MAEs. Combining the findings from six core tasks into a quality filter indicated that only one in seven doses were administered in accordance with standard good practice. Concomitant analysis of the MAE rate with other measures of the medication administration process allowed potential error-producing factors to be explored. However, further work is required to identify the extent of variations in hospital medication systems used to support medication administration.

The next chapter describes a systematic review of UK MAE studies and the effects of methodological variations between studies on reported MAE rates. This is then followed by a national survey of hospital medication systems in English NHS hospitals in chapter four.

Chapter 3. Methodological variations and their effects on reported medication administration error rates

3.1 Introduction

In chapter one, the problem of MAEs was described; MAEs account for the majority of severe patient harm and death reported to the NRLS in the NHS. However, variations between studies of MAEs exist (chapters one and two) and present a potential barrier for increasing medication safety due to limited evaluation of transferability of interventions, risk factors, and MAE rates for benchmarking and monitoring of trends. A preliminary search in April 2010 in the following databases found no systematic literature review of the incidence of MAEs, either completed or in progress: PubMed, Cochrane Library Database of Systemic Reviews, The Database of Abstracts of Reviews of Effects (DARE), Health Technology Assessment Database (HTA), NHS Economic Evaluation Database (NHS EED), and UK Database of Uncertainties about the Effects of Treatments (DUETs). This chapter describes a systematic literature review of UK MAE studies conducted to summarise methodological variations that exist and evaluate their effects on reported MAE rates. This systematic literature review has been published (M^{c}Leod et al., 2013).

3.2 Background

Since the first medication error studies were published in the 1960s (Hill & Wigmore, 1967; Barker & McConnell, 1962), improving medication safety has become a major priority for health care worldwide (World Health Organization, 2008; Department of Health, 2004; Institute of Medicine, 2007; Australian Commission on Safety and Quality in Health Care, 2009). Studies of MAEs can be challenging and resource intensive as direct observation is generally required (Allan & Barker, 1990). In addition, methodological variations between studies are well known, (Allan & Barker, 1990; Barker & McConnell, 1962; Ferner, 2009) which can limit interpretation of findings. Inconsistent MAE definitions, MAE subcategories, denominator definitions and MAE rate calculations exist; these present a potential barrier to interpreting and evaluating the transferability of interventions to reduce MAEs.

Furthermore, the types of doses studied are also likely to affect the MAE rate. Doses that are to be administered via the IV route are widely perceived to be higher risk for MAEs compared to non-IV doses; a recent UK report identified MAE rates of 3-8% for non-IV doses and 49-94% for IV doses (Vincent et al., 2009). However, the true extent of the difference in error rates between IV and non-IV doses is unknown as studies used different methods and definitions. It is also widely believed that MAEs are more likely in children than in adults, but no direct comparison exists (Ghaleb et al., 2006). Consequently, the effects of such commonly accepted risk factors on reported MAE rates have yet to be quantified.

At a macro level, there are important differences between countries in how medication is prescribed, dispensed, and administered, which can also hinder the interpretation of study findings. For example, in the UK, nursing staff are responsible for preparing the majority of doses, including IV doses, on the ward (Brock & Franklin, 2007). By contrast, in the US, pharmacy staff typically prepare the majority of doses and supply these as patient-specific unit-doses. Thus MAEs in the UK would include errors made by the nurse at the preparation

stage while such preparation-related errors in the US are more likely to have been inherited from the earlier dispensing stage.

Considering that MAE studies are important but time-consuming and costly to conduct, it is important to maximise the value of these studies. Thus this chapter describes a systematic literature review of UK MAE studies to identify methodological variations that exist and examine their effects on reported MAE rates. The review used one country as a case study because differences between countries in how medications are prescribed, dispensed and administered, are also likely to affect the prevalence and types of MAEs identified, and thus the exploration of heterogeneity among MAE rates (Dean et al., 1995; Wirtz et al., 2003).

3.3 Aim and objectives

The aim of this systematic literature review was to summarise methodological variations in UK MAE studies and their effects on reported MAE rates. There were four objectives:

(1) To summarise the variation in MAE definitions, MAE subcategories and denominator definitions;
(2) To quantify their effect on reported MAE rates;
(3) To use comparable MAE and denominator definitions to determine overall non-IV and IV MAE rates for adult and paediatric doses;
(4) To quantify the effect of including IV and paediatric doses on reported MAE rates.

3.4 Methods

3.4.1 Setting

In the UK, medications for hospital inpatients are typically prescribed and administered from paper drug charts (Brock & Franklin, 2007). Electronic prescribing is currently rare for

hospital inpatients (although common for discharge and primary care prescribing); few hospitals use barcode verification at the point of administration and unit-dose drug distribution is not used. Instead, nurses administer medications from ward-based stocks, patient-specific supplies from the hospital pharmacy, and/or PODs brought in from home that have been verified by hospital staff.

3.4.2 Search strategy

Nine electronic databases were initially searched for published studies up to and including May 2010: British Nursing Index (from 1985), Cumulative Index to Nursing and Allied Health Literature (from 1981), Embase (from 1980), Health Management Information Consortium (from 1983), International Pharmaceutical Abstracts (from 1970), Medline (from 1950), Pharmline (from 1978), Science Citation Index Expanded (from 1970), Social Science Citation Index (from 1970). The search terms were (medication* OR medicine* OR drug* OR 'near miss' OR 'near misses') AND (error* OR discrepan*) AND adminis* AND (prevalence OR incidence OR harm OR severity OR mortality OR morbidity OR 'adverse event' OR 'adverse events' OR 'adverse drug event' OR 'adverse drug events' OR caus*). 'Medication error' was also included as a mapped thesaurus term in Medline and Embase. Studies were limited to those conducted in humans and published in English. The search was repeated in October 2012 to identify papers published since May 2010; however Pharmline was excluded as it was archived shortly after May 2010.

3.4.3 Study selection process

One reviewer (MM) initially screened all titles and available abstracts identified. A random 10% sample was screened by a second reviewer (BDF) to assess reliability. Only studies reporting empirical MAE rates detected by observation methods were included as observation is generally considered to be the gold standard (Allan & Barker, 1990; Dean &

Barber, 2001). Conference abstracts, case-reports, and studies focusing only on anaesthesia, nutrition or a specific type of MAE were excluded. Full papers of selected studies were retrieved and further examined, including their reference lists. A shortlist of studies was produced. Both reviewers screened these studies and the final set of studies confirmed through discussion.

3.4.4 Data extraction and quality assessment

The two reviewers independently extracted data using standardised forms (appendix 2). Where necessary, authors were contacted for missing information. Discrepancies between reviewers were resolved through discussion and a third reviewer was available if agreement could not be reached. The quality of each study was independently assessed by the two reviewers using the criteria of Allan and Barker which are specific to studies measuring MAE rates (Allan & Barker, 1990). Two criteria for reporting were added: (1) whether or not IV administrations were included as MAE rates for IV doses are known to be higher than for non-IV doses (Vincent et al., 2009), and (2) whether or not paediatric doses were included, as pilot work indicated that not all studies reported this information.

3.4.5 Data analysis

MAE definitions, subcategories and denominator definitions were compared and summarised descriptively. The effect of specific MAE definitions, MAE categorisation and denominator definitions on reported MAE rates was calculated where data were available. A meta-analysis (Neyeloff et al., 2012) of reported MAE rates from studies that used the same MAE and denominator definition was conducted using a random-effects model. An overall MAE rate was calculated separately for non-IV and IV data; for studies that included both types of doses, separate MAE rates were extracted where possible. For studies conducted in multiple countries, only UK data were extracted. Heterogeneity was assessed by calculating

the I^2 index (Neyeloff et al., 2012). Odds ratios were calculated to assess the effect of IV versus non-IV doses and paediatric versus adult doses on MAE rates, where the same error and denominator definitions were used.

3.5 Results

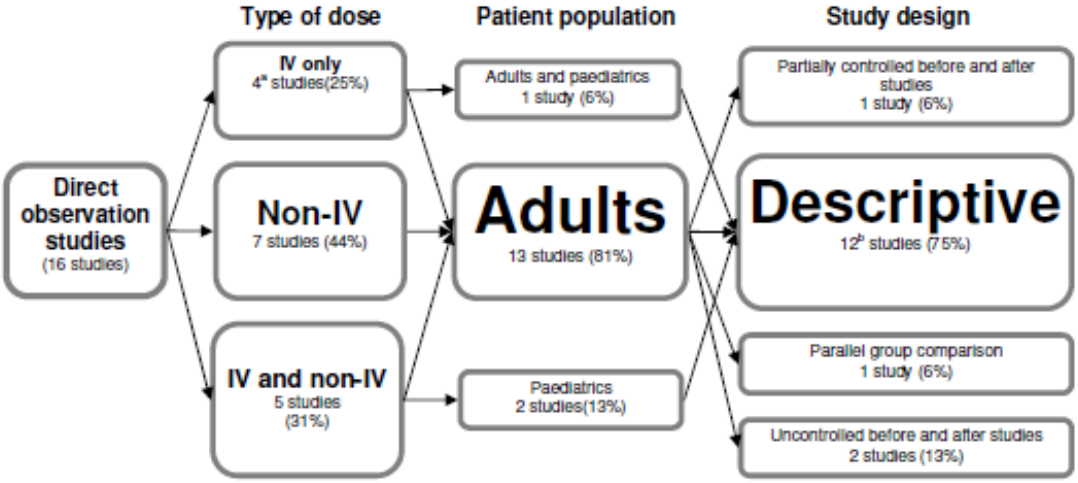
Overall the searches identified 2025 studies; 109 full articles were retrieved and 24 potentially relevant studies subsequently shortlisted. There was 100% agreement between the two reviewers on initial inclusion versus exclusion of a 10% sample (n=203 studies). Of the 24 shortlisted studies, four were excluded because an MAE rate could not be extracted from two studies (Hill & Wigmore, 1967; Valentin et al., 2009), one was conducted in a non-NHS hospital (Haw et al., 2007), and the method of MAE detection could not be ascertained in another (Almond et al., 2002). Twenty studies (Dean et al., 1995; Wirtz et al., 2003; Dean & Barber, 2001; Ridge et al., 1995; Gethins, 1996; Ho et al., 1997; Cavell & Hughes, 1997; Hartley & Dhillon, 1998; Taxis et al., 1999; Dean & Barber, 2000; Bruce & Wong, 2001; Taxis & Barber, 2003b; Franklin et al., 2006; Franklin et al., 2007; Conroy et al., 2007; Ghaleb et al., 2010; Taxis & Barber, 2003a; Franklin et al., 2008; Kelly et al., 2011; Kelly & Wright, 2012) therefore met the inclusion criteria. Of these, four (Dean & Barber, 2001; Taxis & Barber, 2003a; Franklin et al., 2008; Kelly & Wright, 2012) analysed data from previous studies (Dean & Barber, 2000; Taxis & Barber, 2003b; Franklin et al., 2007; Kelly et al., 2011); a final 16 unique studies were included. A third reviewer was not required.

3.5.1 Characteristics and quality of studies

The characteristics of the 16 included studies are outlined in figure 3.1 and table 3.1. The majority were descriptive and conducted in adult settings. Generalisability was limited in eight studies as these were conducted in: (1) only one or two wards (Ho et al., 1997; Cavell & Hughes, 1997; Taxis et al., 1999; Dean & Barber, 2000; Bruce & Wong, 2001; Franklin et al.,

2006; Franklin et al., 2007), (2) wards that received a hospital-specific intervention (Franklin et al., 2007; Franklin et al., 2006), or (3) an unknown number and type of wards (Wirtz et al., 2003).

Figure 3.1 Characteristics of 16 observational studies of medication administration errors. *Weighted font sizes have been used to illustrate approximate proportion of studies between groups that contain more than two studies. [a]One study of parenteral administrations was included as all doses observed for intravenous (IV) doses except for one intramuscular and one subcutaneous dose. [b]Three of 12 studies were comparison studies with other countries.*



In relation to the quality criteria, ten studies reported clear definitions and methods for determining the MAE rate; six did not. Specifically, the following were unclear: (1) the number of MAEs possible per dose (Ridge et al., 1995; Gethins, 1996; Conroy et al., 2007), (2) whether or not dose omissions were included in the denominator (Wirtz et al., 2003; Ridge et al., 1995; Gethins, 1996; Taxis & Barber, 2003b; Conroy et al., 2007), and (3) whether or not 'extra doses'(as defined by Allan and Barker, 1990), were included in the denominator (Wirtz et al., 2003; Ridge et al., 1995; Hartley & Dhillon, 1998; Taxis & Barber, 2003b; Conroy et al., 2007). Participants were told the study objectives in three studies, were not informed in three and partially informed in ten.

Observers were pharmacists in 14 studies, a pharmacist and pharmacy technician in one (Conroy et al., 2007) and a nurse in another (Kelly et al., 2011). Data were collected by one observer in nine studies, two observers in six (Dean et al., 1995; Ridge et al., 1995; Taxis et al., 1999; Dean & Barber, 2000; Franklin et al, 2006; Conroy et al., 2007), and four pharmacists in another (Franklin et al., 2007). Of the seven studies with more than one observer, one (Dean & Barber, 2000) assessed inter-observer reliability (reported in a separate paper)(Dean & Barber, 2001), one reported that "detection of medication errors was comparable between the two observers" (Dean et al., 1995), and five did not report whether or not inter-observer reliability was assessed (Ridge et al., 1995; Taxis et al., 1999; Franklin et al., 2006; Franklin et al., 2007; Conroy et al., 2007). Potential sources of variation were explored in some studies: observations at specific times of day (Ho et al, 1997; Hartley & Dhillon, 1998; Dean & Barber, 2000), days of the week (Ho et al., 1997; Dean & Barber, 2000), time-point of inpatient stay (Ho et al., 1997), timing of administration in relation to when the medication was prescribed (Ho et al., 1997), and nurse-specific variation (Dean & Barber, 2000). All papers reported whether or not IV doses were studied; three studied both dose types but did not report error rates for these separately (Ridge et al., 1995; Conroy et al., 2007; Ghaleb et al., 2010). Ten papers did not specify whether adults, paediatrics, or both, were studied, however all were confirmed as being conducted in adult settings by the relevant authors.

Clinical severity of MAEs was assessed in eight studies: five (Taxis et al., 1999; Dean & Barber, 2000; Taxis & Barber, 2003b; Franklin et al., 2007; Kelly et al., 2011) used the validated method of Dean and Barber (Dean & Barber, 1999), one (Wirtz et al., 2003) used an earlier method developed by Dean (Dean, 1999), one involved an unreported number of clinical pharmacists and the researcher reaching consensus on whether each MAE was minor, moderate or major (Hartley & Dhillon, 1998), and one used the judgement of an experienced

pharmacist researcher to classify each MAE as either minor or potentially serious (Franklin et al., 2006). All severity assessments were based on potential (rather than actual) harm.

No obvious trend in MAE rates over time was identified, table 3.1. A forest plot of non-IV studies which used the same MAE definition and denominator also showed no apparent trend in MAE rates over time (figure 3.2). A scatterplot of the same studies revealed no discernible correlation between MAE rates and sample size (figure 3.3).

Figure 3.2 Forest plot of 12 reported medication administration error (MAE) rates from eight UK observational studies of non-IV doses that used the same error definition, denominator definition and error rate calculation.

Study	Sample (OEs)	% MAE rate of OEs
Dean et al (1995)	2765	
Cavell and Hughes (1997) (handwritten)	1206	
Cavell and Hughes (1997) (computer)	1295	
Ho et al (1997)	2170	
Taxis and Barber (1999)	842	
Dean and Barber (2000) (drug trolley)	3576	
Dean and Barber (2000) (bedside locker)	2491	
Franklin et al (2006) (pre web-based education)	1165	
Franklin et al (2006) (post web-based education)	1282	
Franklin et al (2007) (pre EPMA)	1473	
Franklin et al (2007) (post EPMA)	1139	
Kelly (2011)	2129	
Pooled MAE rate (meta-analysis, random-effects model)	21,533	

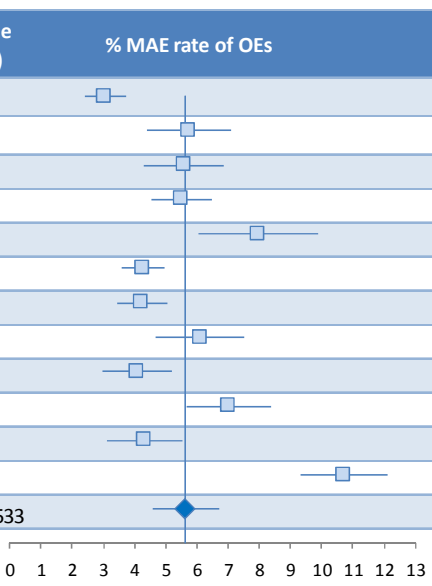


Figure 3.3 Scatterplot of 12 reported medication administration error (MAE) rates from eight comparable UK studies of non-IV doses.

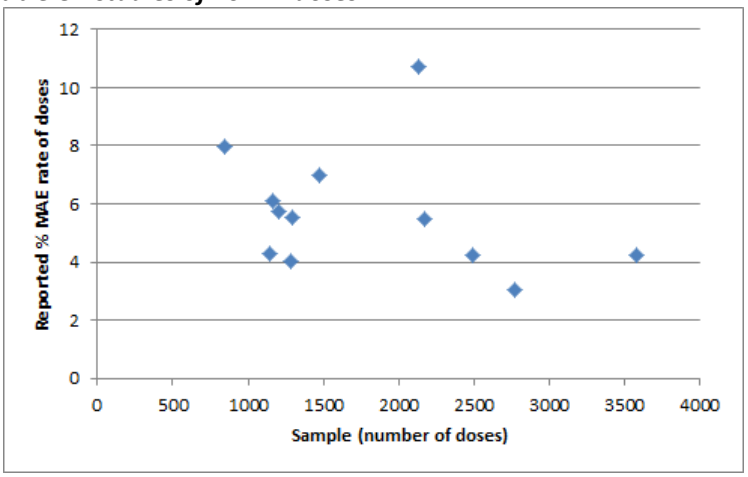


Table 3.1 Characteristics of 16 UK observational studies and reported medication administration error (MAE) rates. *Wrong time errors were excluded from reported MAE rates where applicable.

Study	Study setting	Data collection	Were participants told the purpose of the study?	IV or non-IV doses	Sample size	Reported MAE rate* (95% CI)
Dean et al 1995	1 hospital, 6 wards: 2 medical, 2 surgical, 2 MfE.	Consecutive weekday drug rounds (May and June 1993).	Partially (a study of medication administration and work sampling conducted concurrently).	Non-IV	2756 OE	3.0% (2.4 to 3.7)
Ridge et al 1995	1 hospital, 6 wards: 2 medical, 2 surgical, 2 MfE.	One week on each ward (at least 10 drug rounds), between January and April 1993.	No (work sampling study).	Both	3312 drug administrations	3.5% (2.9 to 4.1)
Gethins 1996	1 hospital, 5 wards: 4 medical, 1 renal.	6 week period.	No (a time and motion survey).	Non-IV	2000 drug administrations	2.8%
Ho et al 1997	1 female MfE ward.	Two 8-day periods with one week break in between.	Partially (a study of the problems associated with the medication distribution system).	Non-IV	2170 OE	5.5% (4.5 to 6.4)
Cavell and Hughes 1997	2 hospitals, 2 medical wards.	42 drug rounds on ward with handwritten charts (H). 35 drug rounds on ward with computer-printed administration form (C).	Partially (a study of computerised prescribing on the drug use process).	Non-IV	1206 OE (H) 1295 OE (C)	5.5% (H) 5.7% (C)
Hartley and Dhillon 1998	1 hospital. 3 wards: 2 surgical, 1 medical.	39 consecutive days in June and July 1996.	Partially (a study to understand the constraints the nurses operated under and to improve the provision of information for their needs).	IV	320 prescribed doses	26.9% (20.3 to 30.7)
Taxis and Barber 1999	1 hospital, 2 general medical.	5 weekdays on each ward in May and July 1997. All scheduled drug rounds except where two nurses administered using separate trolleys.	Partially (a study of advantages and disadvantages of each system).	Non-IV	842 OE	8.0% (6.2 to 9.8)
Dean and Barber 2000	1 hospital: 1 vascular surgery and 1 renal medical ward.	Total 27 days before bedside medication lockers were implemented, and 17 days post. All four scheduled drug rounds seven days a week (January to June 1998).	Partially (a study to find out how often medication was unavailable, could not be found, or whether any other problems occurred).	Non-IV	3576 OE (pre) 2491 OE (post)	4.3% (pre) 4.2% (post)
Bruce and Wong 2001	1 acute admissions ward.	4 weeks, each weekday in December 1998.	No (a study of time spent on drug administrations).	IV (except 1 SC, 1 IM)	107 OE	10.3% (3.8 to 14.9)

Table 3.1 continued. Characteristics of 16 UK observational studies and reported medication administration error (MAE) rates. *Wrong time errors were excluded from reported MAE rates where applicable.

Taxis and Barber 2003	2 hospitals, 10 wards: 1 renal, 2 medical, 1 CTS, 1 surgical, 1 ICU, 1 oncology, 1 neonatal, 1 CICU, and 1 paediatric.	6-10 consecutive days on each ward between June and December 1999. Included weekends and all times of drug rounds on each ward.	Partially (a study of common preparation and administration problems of IV drugs).	IV	430 observed doses	49% (45 to 54)
Wirtz et al 2003	1 hospital. Number and types of ward not stated.	6 consecutive days in each ward, May - June 2000.	Partially (a study of problems associated with preparing and administering IV drugs).	IV	77 preparations, 63 administrations	22% (prep) (13 to 31) 27% (admin) (16 to 38)
Franklin et al 2006	1 mixed medical ward.	4 weeks pre internet-education for nursing staff (June 2004), 4 weeks post (Oct/Nov 2004).	Partially (a study of drug administration problems).	Both	1188 OE (pre) 1308 OE (post)	6.9% (pre) 5.0% (post)
Franklin et al 2007	1 general surgical ward.	2 weeks pre-EPMA (spring 2007) and 2 weeks post-EPMA (spring 2008).	Partially (a study of any problems associated with the medication system).	Both	1644 OE (pre) 1178 OE (post)	8.6% (pre) 4.4% (post)
Conroy et al 2007	1 children's hospital. Included PICU, NICU, medical, surgical, ED.	6 weeks, usually two drug rounds each weekday.	Yes	Both	752 administrations	1.2%
Ghaleb et al 2010	5 hospitals, 10 wards: 4 medical, 1 adolescent, 2PICU, 2NICU, 1surgical	2 week period on each ward (2004/2005) each day, including weekends.	Yes	Both	1554 doses; 2249 OE	27.6% of doses 19.9% of OE (17.5 to 20.7)
Kelly et al 2011	4 hospitals, 8 wards: 1 MfE and 1 stroke ward per hospital.	March to June 2008. Morning and lunchtime drug rounds on some weekdays and weekends.	Yes	Non-IV	2129 OE	10.7%

[a] comparison study of UK and USA hospital (only UK data is presented)
[b] comparison study of UK and German hospital (only UK data is presented).
CICU, cardiac intensive care unit; CTS, cardio-thoracic surgery; ED, emergency department; EPMA, electronic prescribing and medication administration system; ICU, intensive care unit; IM, intramuscular; IV, intravenous; MfE, medicine for the elderly; NICU, neonatal intensive care unit; OE, opportunities for error; PICU, paediatric intensive care unit; SC, subcutaneous.

3.5.2 MAE definitions

Three different overall MAE definitions were identified. Fourteen studies (Dean et al., 1995; Wirtz et al., 2003; Ridge et al., 1995; Gethins, 1996; Ho et al., 1997; Cavell & Hughes, 1997; Taxis et al., 1999; Dean & Barber, 2000; Bruce & Wong, 2001; Taxis & Barber, 2003b; Franklin et al., 2006; Franklin et al., 2007; Ghaleb et al., 2010; Kelly et al., 2011) used Allan and Barker's (1990; p558) definition: "a deviation from the physician's medication order as

written on the patient's chart". Of these, three (Wirtz et al., 2003; Taxis & Barber, 2003b; Ghaleb et al., 2010) expanded this American-based definition to include 'any deviation from standard hospital policy or the manufacturer's instructions', and one (Kelly et al., 2011) included three additional drug administration related guidance documents to evaluate the 'appropriateness of administration'. The additional specifications relating to hospital policy, manufacturer's instructions, and other drug administration guidance documents made the definition more specific for studying IV doses, paediatric doses and doses administered to patients with dysphagia in the UK. One study (Hartley & Dhillon, 1998) used a circular definition: "error in an administered dose or an omitted dose", and one (Conroy et al., 2007) used an outcome-based but general definition: "preventable events that may cause or lead to inappropriate medication use or patient harm". Observers intervened to prevent all identified MAEs in three studies (Cavell & Hughes, 1997; Hartley & Dhillon, 1998; Conroy et al., 2007) and only for potentially serious errors in the remaining 13; all interventions were included as MAEs.

Inconsistencies in what was included as an MAE were identified, even when the same definition was used. Four specific variations were identified, table 3.2. The most significant and divisive amongst researchers was 'wrong time' errors. Based on data reported in one single-centre study, including wrong time errors of over 30 minutes from the time for which the dose was due increased the MAE rate from 27% to 69% of 320 IV doses (Hartley & Dhillon, 1998). The effect of including wrong time errors in non-IV doses was not assessed as relevant studies did not report the number of doses with wrong time errors only. Nonetheless, including wrong time errors is likely to substantially increase the reported MAE rate as doses administered over 60 minutes from the time for which the dose was due occurred in 13-50% of a total of 9054 non-IV doses (Dean et al., 1995; Ho et al., 1997; Cavell & Hughes, 1997; Kelly et al., 2011).

Table 3.2 Summary of variations associated with medication administration error (MAE) inclusion/exclusion criteria in 16 UK observational studies and their effect on the reported MAE rate.

Type of variation in MAE inclusion/exclusion criteria	Number of studies that included the following as an MAE	Number of studies that excluded the following as an MAE	Number of studies that did not report whether or not the following were included as an MAE	Effect of variation on reported MAE rate
Wrong time	6	5	5	Including wrong time errors of over 30 minutes from the time for which the dose was due increased the reported MAE rate from 27 to 69% of 320 intravenous doses (Hartley & Dhillon, 1998). Other studies did not report these data separately.
Omission due to patient not on ward	3	1	12	Unknown, as studies did not report these data separately.
Doses left at the patient's bedside without nurse witnessing consumption	1	4*	11	These accounted for 2.8% of 1554 paediatric doses in one multi-centre study (Ghaleb et al., 2010). If the frequency of doses left at the bedside are similar in adult hospital settings, then inclusion of these as MAEs would potentially increase the MAE rate by up to 2.8% of doses observed.
Omission for clinical reasons	1	6	9	These occurred in 0.2% of 2000 non-intravenous doses in one study (Gethins, 1996) and thus their exclusion in other MAE studies is unlikely to have a significant impact on the reported MAE rate.

**One study excluded leaving a dose at the bedside as a MAE initially but included these as MAEs if the dose was still at the bedside by the time the researcher leaves the ward* (Kelly et al., 2011).

3.5.3 MAE subcategories

Forty-four different MAE subcategories were identified, with a median of 11 per study (range 3 to 16), table 3.3. In some cases, differences in subcategories reflect different ways of classifying the same errors. For example, MAE subcategories such as 'wrong diluent' and 'wrong solvent' can be considered more detailed subcategories of a broader subcategory:

'wrong preparation technique'. Furthermore, in studies where only one MAE was allowed for each dose, none specified the hierarchy used to decide how the subcategory was allocated if more than one error was observed for the same dose. Although the classification should not affect the overall MAE rate, care should be taken when comparing specific MAE subcategories across studies.

Different researchers also used the same term to mean different things and different terms to mean the same thing. This mainly concerned 'unordered drug' errors (also known as 'unauthorised drug' and 'unprescribed drug'). One study used 'unauthorised drug' to include 'wrong drug', 'wrong patient' and 'administration of a drug without a valid prescription' (Hartley & Dhillon, 1998). However, other studies differentiated 'unauthorised drug' from 'wrong drug' by stating that the former involves the administration of a drug where no medication order exists, while the latter involves administration of a different drug against an existing medication order (Wirtz et al., 2003; Taxis et al., 1999; Dean & Barber, 2000; Franklin et al., 2006; Ghaleb et al., 2010; Kelly et al., 2011). An 'unauthorised drug' error is also generally differentiated from an 'extra dose' error which is administering an extra dose of a prescribed drug, for example, giving a medication twice a day instead of once a day (Allan & Barker, 1990).

In some cases, differences in MAE subcategories used may reflect disparities in the types of error included. One study considered dose omissions, a common MAE subcategory, as a "violation of procedure" and differentiated these from MAEs (Conroy et al., 2007). Including dose omissions in this study would increase the MAE rate from 1.2% to 5.6% of 742 drug administrations. There were also studies that included some procedural violations within established MAE subcategories, for example, not wearing gloves was included in a 'wrong preparation technique' subcategory (Hartley & Dhillon, 1998; Bruce & Wong, 2001), but was

not included as an MAE in other studies. However, data were not reported separately in the relevant studies and therefore their effect on the reported MAE rate was not determined.

Several studies additionally reported a breakdown of specific MAE subcategories based on the reason for error. Although the causes of MAE are outside the scope of this literature review, these additional subcategories were frequently reported and provide an important role for understanding MAE rates. For example, o*mission due to unavailability* was commonly included as a subset of omissions and accounted for 52-67% of a total of 12,993 non-IV dose omissions (Dean et al., 1995; Gethins, 1996; Ho et al., 1997; Dean & Barber, 2000).

Table 3.3 Medication administration error (MAE) subcategories included in 16 UK observational studies.

	MAE subcategories (as per terminology used in studies)	Dean et al 1995	Ridge et al 1995	Gethins 1996	Ho et al 1997	Cavell & Hughes 1997	Hartley & Dhillon 1998	Taxis et al 1999	Dean & Barber 2000	Bruce & Wong 2001	Taxis & Barber 2003a	Wirtz et al 2003	Franklin et al 2006	Franklin et al 2007	Conroy et al 2007	Ghaleb et al 2010	Kelly 2011	Total
1	*Omission	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	15
2	*Wrong dose / improper dose	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓		✓	✓	14
3	*Wrong dosage form / wrong form / wrong preparation selected / wrong pharmaceutical form / wrong formulation	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓			✓	13
4	*Deteriorated drug / expired drug	(✓)	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓			✓	12
5	*Extra dose / unordered dose	✓	✓		✓		✓	✓	✓				✓	✓		✓	✓	10
6	Wrong drug	✓			✓	✓		✓	✓			✓	✓	✓		✓	✓	10
7	*Unordered drug /unauthorized drug/unprescribed drug		✓			✓	✓	✓	✓	✓		✓	✓			✓	✓	10
8	*Wrong route	✓	✓				✓		✓	✓		✓	✓	✓			✓	9
9	*Wrong dose preparation/ wrong preparation technique / wrong technique / wrong preparation		✓	✓	✓	✓	✓			✓		✓				✓		8
10	*Other / miscellaneous	✓			✓	✓						✓	✓			✓	✓	7
11	Wrong patient	(✓)		✓		✓					✓			✓				4
12	*Wrong rate of administration						✓			✓		✓	✓					4
13	Drug incompatibility									✓	✓	✓	✓					4
14	*Wrong time +/- 30 minutes			✓	(**)	✓	✓							(**)				3
15	*Wrong administration technique					✓	✓									✓		3
16	Wrong time +/- 1 hour	(**)	(**)		(**)	✓				✓		(**)		(**)			✓	3
17	Fast IV bolus												✓	✓				2
18	Wrong diluent												✓	✓				2
19	Wrong time - not specified													✓		✓		2
20	Unauthorised			✓														1
21	Wrong preparation			✓														1
22	Administration without a valid prescription					✓												1
23	Incomplete labelling									✓								1
24	Wrong base solution content									✓								1
25	Errors in solvent/diluent										✓							1
26	Fast administration (via a central line)										✓						1	
27	Fast administration (via a peripheral line)										✓							1
28	Other administration errors										✓							1
29	Other preparation errors										✓							1
30	Preparation of an unauthorised drug										✓							1
31	Preparation of wrong dose										✓							1
32	Preparation of wrong drug										✓							1
33	Wrong dose preparation											✓						1
34	Wrong solvent												✓					1
35	Wrong volume of diluent												✓					1
36	Wrong volume of solvent												✓					1
37	Errors with inhalers/nebuliser													✓				1
38	Errors with oral/gastrostomy drug administration													✓				1
39	Errors with IV drug administration													✓				1
40	Incorrect rate of IV administrations															✓		1
41	Left drug by patient's bedside without checking drug administration															✓		1
42	Omission of nurses' signature															✓		1
43	Wrong dose preparation and administration																✓	1
44	Wrong time +/- 2 hours		(**)		(**)									(**)				0
TOTAL		7	8	9	8	12	11	7	8	12	11	12	16	11	3	12	11	

** indicate subcategories that were listed by Allan and Barker[11] ✓reported by the study, (✓) reported in a sub-analysis of causes of MAEs and not as an MAE subcategory, (**) measured but not considered an error. IV, intravenous.*

3.5.4 Denominators used to determine MAE rates

We identified four denominators and three main differences between them which may affect interpretation of reported MAE rates. The four denominators were the total number of: (1)'opportunities for error' (OE) defined as the "sum of all doses ordered plus all the unordered doses given" (Allan & Barker, 1990), (2) 'drug administrations', (3) 'prepared and/or administered doses', and (4) 'prescribed doses'. The first difference between the denominators is whether or not dose omissions were included. All ten studies (Dean et al., 1995; Ho et al., 1997; Cavell & Hughes, 1997; Taxis et al., 1999; Dean & Barber, 2000; Bruce & Wong, 2001; Franklin et al., 2006; Franklin et al., 2007; Ghaleb et al., 2010; Kelly et al., 2011) that used OE and one (Hartley & Dhillon, 1998) that used 'prescribed doses' as the denominator included dose omissions, while it was unclear in the remaining five (Wirtz et al., 2003; Ridge et al., 1995; Gethins, 1996; Taxis & Barber, 2003b; Conroy et al., 2007) whether or not dose omissions were included. Dose omissions accounted for 0-13 % of a total of 934 IV doses (Wirtz et al., 2003; Hartley & Dhillon, 1998; Bruce & Wong, 2001; Taxis & Barber, 2003b) and 1.8-5.1% of a total of 16,465 non-IV doses (Dean et al., 1995; Cavell & Hughes, 1997; Taxis et al., 1999; Dean & Barber, 2000; Kelly et al., 2011), therefore excluding dose omissions from the denominator will inflate the reported MAE rate. The second difference was whether or not extra doses were included: ten studies that used OE included extra doses in the denominator, but it was unclear in the remaining six. Despite this variation, extra doses are relatively rare and therefore unlikely to substantially affect the reported MAE rate. The third difference is whether or not each dose was split into preparation and administration. This was generally a feature of studies that included IV and/or paediatric doses. Seven of the 10 studies that used an OE as the denominator counted one OE per dose (Dean et al., 1995; Ho et al., 1997; Cavell & Hughes, 1997; Taxis et al., 1999; Dean & Barber, 2000; Franklin et al., 2006; Kelly et al., 2011) (all were studies of non-IV doses) and three allowed up to two OEs per dose (Bruce & Wong, 2001; Franklin et al., 2007; Ghaleb et al., 2010) (all included IV doses, two in adults and one in paediatrics). In the paediatric study

where up to two OEs were possible per dose, researchers reported that MAEs occurred in 19.1% of OE and 27.6% of doses (Ghaleb et al., 2010). The effect of allowing up to two OEs per dose in this study therefore resulted in a lower calculated MAE rate.

3.5.5 MAE rates

Non-IV versus IV doses

A meta-analysis of 21,533 adult non-IV OEs from eight studies revealed MAEs occurred in 5.6% for non-IV OEs (95% CI, 4.6-6.7%) (table 3.4). Heterogeneity between studies was relatively low (random effects model I^2=19%). Nine MAE rates for IV doses were extracted; however a meta-analysis of three MAE rates was conducted from two studies only as it was inappropriate to include studies that used different error and denominator definitions. MAEs occurred in 35% of a total of 156 adult OEs (95% CI 2-68%) (Bruce & Wong, 2001; Franklin et al., 2007). Heterogeneity between studies was low (random effects model I^2=0), however this was based on a small sample of IV OEs which resulted in a wide 95% CI. Based on these limited data, IV doses were estimated to be five times more likely to be associated with an MAE than non-IV doses (pooled OR 5.1; 95% CI 3.5-7.5).

Adult versus paediatric doses

Of the three studies that included paediatric doses, two reported IV and non-IV data together (Conroy et al., 2007; Ghaleb et al., 2010) and one study combined adult and paediatric IV doses (Taxis & Barber, 2003b). It was thus inappropriate to perform a meta-analysis of paediatric MAE rates for comparison with adult MAE rates.

Table 3.4 Summary of 29 medication administration error (MAE) rates from 16 direct observation studies.

Type of doses	Numerator	Denominator term (definition)	Meta-analysis of MAE rate (95% CI)	Studies
Non-IV doses	MAE definition based on Allan and Barker 1990.	**Opportunity for error** (Total number of doses given plus any doses ordered but omitted)	**5.6%** **(4.6 to 6.7)**	Cavell and Hughes 1997 Dean and Barber 2000 Dean et al 1995 Franklin et al 2007 Franklin et al 2006 Ho et al 1997 Taxis and Barber 1999 Kelly et al 2011
		Drug administration *("Drugs administered from the drug trolley")*	**3.2%**	Gethins 1996
IV doses only	MAE definition based on Allan and Barker 1990.	**Opportunity for error** (Total number of doses given plus any doses ordered but omitted)	**35%** **(2 to 68)**	Franklin et al 2006 Bruce and Wong 2001* (all IV doses except one SC and one IM)
	MAE (Allan and Barker 1990) *plus "any deviation from the hospital's intravenous policy or the manufacturer's instructions".*	**Drug prepared and/or administered** (Total number of doses prepared and/or administered)	**22%** of preparations	Wirtz et al 2003
			27% of administrations	
			49%	Taxis and Barber 2003a (adults and paediatrics)
	"Error in an administered dose or an omitted dose"	**Prescribed doses** *("Total number of prescribed doses")*	**16.7%**	Hartley and Dhillon 1998*
IV and non-IV doses (proportion of IV and non-IV doses were different between studies)	MAE (Allan and Barker 1990)	**Opportunity for error** (Total number of opportunities for error for doses given "*plus any doses ordered but omitted*.")	**6.0%** (up to 2 OEs per dose)	Franklin et al 2007 Franklin et al 2006
	MAE (Allan and Barker 1990) plus *"any deviation from standard hospital policy & procedure".*		**19.1%** (>1 MAE per OE possible and up to 2 OEs per dose)	Ghaleb et al 2009 (paediatrics)
	"Preventable events that may cause or lead to inappropriate medication use or patient harm"	**Drug administration** (Total number of drug administrations)	**1.2%** (excluded 141 (18.8%) violations in 752 drug administrations)	Conroy et al 2007 (paediatrics)
	MAE (Allan and Barker 1990).		**3.5%** (excluded wrong administration rate errors)	Ridge et al 1995

*All reported error rates were calculated using: number of opportunities for error (OE) with at least one MAE divided by the total number of OEs unless where stated in the table. *indicates studies where the MAE rate was manually adjusted from the reported MAE rate presented in the study which was based on >1 MAE for each OE. All MAE rates exclude timing errors. All studies were conducted in adult patient populations unless otherwise stated in the table. IM, intramuscular; IV, intravenous; SC, subcutaneous.*

3.6 Discussion

3.6.1 Methodological variations

While methodological variations between studies are widely known, no literature review has systematically summarised and quantified their effects on reported MAE rates. Using the UK as a case-study, a number of methodological variations between studies were identified, even within one country. Some differences reflect the objectives of specific studies; the rationale for other differences was less clear. The effects of some methodological variations on the reported MAE rate were quantified. Notably, IV doses were five times more likely to be associated with a MAE than non-IV doses. While the 95% CI for the pooled MAE rates for non-IV and IV doses overlap, the 95% CI for the OR does not cross zero, suggesting that the odds of error was significantly different for non-IV and IV doses.

The findings highlight the importance of considering a number of methodological details when interpreting studies of MAE rates. More research is required to quantify other methodological effects on reported MAE rates, for example: (1) whether or not nurse participants were fully, partially or not informed of the study objectives, (2) type of observer, for example, a pharmacist and/or a nurse, and (3) the type of medication order included in studies, for example, regular and/or 'when required' medication orders.

3.6.2 MAE rates and practical implications

The meta-analysis revealed an overall MAE rate of 5.6% for non-IV OEs and 35% of IV OEs in UK hospitals. The pooled estimate of the MAE rate for non-IV doses was based on a relatively homogenous, large sample of OEs in adult patients from a wide range of settings and therefore may be useful for benchmarking and monitoring UK hospital MAE rates. In contrast, there was a limited sample and wide confidence interval for IV doses.

Sub-analysis of MAE rates for non-IV doses showed no apparent trends over the past 15 years. However, interpretation is limited as studies cannot be compared directly due to their methodological variations. Studies measuring MAE rates at frequent regular intervals using consistent methods are required to monitor long-term trends; this may require coordination at a local and national level in order to maximise the utility of the data collected beyond that of a 'standalone descriptive study'.

Limited numbers of UK studies and insufficient reporting in all three paediatric studies prevented calculation of overall MAE rates for paediatric non-IV and IV doses separately. Future studies measuring and reporting separate MAE rates for non-IV and IV doses in paediatrics are required to assess the effect of including paediatric doses on reported MAE rates.

3.6.3 Suggestions for future studies of MAEs

A suggestion, based on the current study findings, is for future studies to use definitions and methods for measuring MAEs that are based on those used previously. This not only allows comparison with past findings but also facilitates the capture of new errors that arise. For studies that include IVs, paediatrics and other doses that require multiple manipulations, for example, for patients with dysphagia, it might be useful to build on the work by Taxis et al (2003) by separating MAE subcategories according to preparation and administration stage. This will develop our understanding of where MAEs occur and allow comparisons to be made across different medication doses and systems.

Based on Allan and Barker's (1990) MAE definition, subcategories should probably be assigned from the perspective of the medication order where practical (rather than the patient's perspective). Although the patient's perspective plays a vital role in assessing the

quality of health care in many cases, the medication order viewpoint is advocated to provide a practical approach to categorising MAEs which also allows for better comparison with previous studies. The perspective is important to distinguish between errors such as administering a 'wrong drug' to the right patient (patient perspective) and administering the right drug (according to the medication order used at the time of administration) to the 'wrong patient'; the former is an error at the preparation stage and the latter is an error at the administration stage.

To improve the clarity of 'unordered/unauthorised drug' errors, one suggestion would be to split this subcategory into three: 'wrong drug', 'wrong patient' and 'administration without a medication order'. A 'wrong drug' error occurs when an incorrect drug is selected against an existing medication order, a 'wrong patient' error occurs when the correct drug is selected but administered to a different patient and 'administration without a medication order' is giving a drug to a patient against no existing medication order (for example, giving a dose before it has been prescribed on the drug chart).

The use of OE as the denominator has been advocated for determining medication error rates in general (Brown et al., 2008) and for MAE rates specifically (Allan & Barker, 1990). For calculating MAE rates, the proportion of OE with at least one MAE was found to be the most practical and easily interpretable. Consequently another suggestion would be to use this calculation either alone or in addition to other MAE rate calculations. In studies where each dose may be associated with more than one OE, the proportion of doses given (or omitted) with at least one MAE should also be reported where possible.

Finally, based on the findings in this review and experience in conducting observation studies, a set of reporting guidance to support future researchers is proposed, table 3.5. This is intended for use in conjunction with standard good practice for reporting, and is designed

to be non-prescriptive as a considerable part of a study's design and subsequent reporting will depend on the objectives. Further work is needed to evaluate this.

Table 3.5 Suggested reporting criteria for future studies that involve measuring medication administration error (MAE) rates adapted from Allan and Barker (1990).

Parameter	Suggestions for reporting in future MAE studies:
Method of data collection	1. Whether direct observation, incident reports and/or chart review was used 2. Number, profession and experience of data collectors 3. Whether or not inter-observer reliability was assessed if more than one data collector, and how this was assessed
Type of doses	4. Whether or not intravenous (IV) doses were included 5. Proportion of IV doses, if both IV and non-IV were included 6. Whether or not regular, when required and/or 'once-only' medication orders were included
Patients	7. Whether adults and/or paediatric patients were studied 8. Proportion of adult and paediatric doses if both were included
Medication administration errors	9. Operational definition accompanied by a set of guidance with examples 10. Explicit inclusion and exclusion criteria. Examples include stating whether or not the following were considered to be an MAE: i. Time of administration in relation to that prescribed (for regular and 'once-only' medication orders) ii. Omissions for clinical reasons such as those determined by the nurse, lack of IV access and patient refusal iii. Omission due to patient not on the ward iv. Procedural-related violations such as not checking a patient's identity, leaving a dose at the patient's bedside without observing administration, not labelling a syringe, administering without a valid prescription and not documenting administration v. Errors prevented by the observer, patient, nurse and other health care professionals 11. Number of errors possible per dose 12. Number of doses with at least one error if more than one error is possible per dose 13. Types of medication orders involved: regular, 'when required', 'once-only' medication, medications ordered separate to the drug chart
MAE subcategories	14. Operational definitions for error subcategories used 15. For studies where each dose can only be associated with one error, state the hierarchy for deciding how the MAE category should be allocated if more than one error occurs in the same dose 16. The number of MAE detected in each category
Denominator	17. Operational denominator definition accompanied by a set of guidance with examples 18. Explicit inclusion and exclusion criteria for including doses in the denominator. Examples include stating whether or not the following were included in the denominator: i. Omission of a prescribed dose ii. Administration of an extra dose of a prescribed drug iii. Leaving a dose at the patient's bedside without observing administration iv. Non-medication items, for example, support stockings and dietetic products v. Oxygen and other medical gases 19. Types of medication orders included: regular, 'when required', 'once-only' medication, medications ordered separate to the drug chart 20. Relationship between denominator used and a dose, if dose is not used as the denominator 21. Number of doses excluded from the study
MAE rate	22. How the MAE rate was calculated
Other	23. Whether or not the clinical severity of MAEs was assessed, and how

3.6.4 Limitations

Few studies of IV doses and substantial heterogeneity meant findings from only two studies were used to calculate the overall MAE rate for IV doses and there were insufficient data to explore the differences between adult and paediatric MAE rates. Only UK-based studies were included and therefore the overall MAE rates cannot be extrapolated to other countries. Finally, 11 of the 16 included studies were co-authored by PhD supervisors BDF and/or NB. This was identified as a potential limitation as this may be perceived as a source of bias. However, this was also one of the strengths of the current review, as their experience has facilitated review of the studies by MM to a high level of detail.

3.7 Conclusion

The UK literature was used to summarise methodological variations between studies within one country and their effect on reported MAE rates were evaluated. A number of methodological and reporting recommendations can be applied to other countries. Overall, the findings may be useful for making future MAE studies more transparent and comparable.

Chapter 4. A national survey of medication systems and processes in English NHS hospitals

4.1 Introduction

Systems and processes by which medications are prescribed, ordered, distributed and administered have a great impact on patient safety and MAEs (Ammenworth et al., 2008; Franklin et al., 2007; McRobbie et al., 2003; Dean & Barber, 2000; Cavell & Hughes, 1997; Dean et al., 1995). Surprisingly few studies have measured system and/or process changes on UK MAE rates (chapter three). Those studies that exist, suggests different systems contribute to MAEs in different ways (Franklin et al., 2007; Cavell & Hughes, 1997; Taxis et al., 1999; Dean et al., 1995). However, the extent of use of many medication systems and processes within the NHS is currently unknown; this presents a barrier for assessing the generalisability of interventions to reduce MAEs across the NHS, and also for exploring the advantages and disadvantages of systems variation for further research to reduce MAEs. This chapter describes a national survey that was conducted to identify the extent of variation in medication systems used in English NHS hospitals.

4.2 Background

Against a backdrop of increasing financial pressures on the NHS and greater awareness of the need to increase patient safety, there is an urgent need to maximise benefits from interventions that reduce risk and can be applied across a range of settings. In the past, national initiatives such as the use of PODs, OSD, and the introduction of patient bedside medication lockers have been implemented in hospitals with some success (Audit Commission, 2001; Department of Health, 2000b; Lummis et al., 2006). These interventions evolved from the recognition of common problems across the NHS. However, the extents to which local problems are generalisable to the wider NHS are not always clear because systems-based similarities and differences between hospitals have not been described (chapter one). Furthermore, different types of hospital medication systems have been associated with different effects on MAEs.

Different hospital drug distribution systems have previously been associated with different MAE rates and also in the types of MAEs that occur (Means et al., 1975; Dean et al., 1995; Taxis et al., 1999). More recently advances in technology, in the form of automation, EPMA, and BCMA systems, and their subsequent adoption has also contributed to potential systems-based variation between hospitals. In turn, these have been associated with different effects on reported MAE rates (Schwarz & Brodowy, 1995; Paoletti et al., 2007; DeYoung et al., 2009; Poon et al., 2010; Franklin et al., 2007). Thus, knowing the extent of such systems-based variation would facilitate the prioritisation and development of systems-based interventions to reduce MAEs.

Unlike in the US (Pedersen et al., 2012; 2011), there has been no national survey of hospital medication systems used to support medication administration in UK hospitals. A recent survey (Frontini et al., 2012) of hospital medication procurement and distribution in Europe suggested that 37.5% of UK hospital pharmacists provided a unit-dose service. However, the

response rate from the UK was very low; 34.5% of questionnaires sent were returned and only 8.8% were usable after adjusting for the number of unanswered questions. Furthermore, it was unclear what was meant by a 'unit-dose service' and how the question was framed in the survey. A unit-dose service in the MAE-related literature and in hospital practice generally refers to the unit-dose preparation of all medication doses in a hospital; however some hospitals provide a unit-dose preparation service for specific drugs only, such as in the production of sterile unit-doses of chemotherapy and in the provision of a centralised intravenous additive service. Separately, a survey of clinical pharmacy services in UK NHS hospitals (Cotter et al., 1994) reported the extent to which a wide range of activities were carried out by pharmacy staff. Among the findings, the survey identified that 9% of hospitals had a resident on-call pharmacist and 88% had a non-resident on-call pharmacy service that provided advice and medication supply support outside of pharmacy opening hours. However, the data is now over 20 years old and no other national survey of medication administration related services and systems have been conducted since then.

The gap in the knowledge of the extent to which different systems are used in hospitals present a potential barrier for prioritising and developing systems-based interventions to reduce error. Thus, a national survey of hospital medication systems in English NHS hospitals was conducted and is described in this chapter.

4.3 Aim and objectives

The aim of the present survey was to describe the medication administration related systems and processes currently used in English NHS hospitals. There were three objectives:

(1) To summarise the systems and processes used for prescribing, obtaining, storing, and administering medications on general medical and surgical inpatient wards;

(2) To identify intra- and inter-hospital similarities and variations in systems and processes used for obtaining, storing, and administering medications on inpatient wards;

(3) To summarise local strategies currently used with the aim of reducing MAEs in English NHS hospitals.

4.3 Methodology

A descriptive survey was conducted as these are routinely used in health service research to identify (i) what the characteristics of a target population may be (ii) what proportion of a population have a certain characteristic or opinion and (iii) how often certain characteristics or events occur together (Oppenheim, 1992). As such, survey findings often contribute to the generation of inferences regarding potential causal relationships for further investigation. This section describes three main methodological considerations that contributed to the study: (1) analytic framework, (2) approach to the survey, and (3) questionnaire development.

4.3.1 Analytic framework

An analytic framework was developed to define the scope of this study, guide development of survey questions and subsequent data analysis. Initially, this involved identifying key processes required for medication administration on inpatient wards with both PhD supervisors (BDF and NB), and then separately with two senior hospital pharmacists; each had 10-20 years of hospital pharmacy experience, and a working knowledge of medication processes and resources used on a variety of wards in multiple hospitals. Main systems and resources used to support the processes identified were then listed. These were based around four key questions:

1. What proportion of hospitals use paper drug charts and/or an EPMA system?

2. What pharmacy services are provided to supply medication for inpatient use in hospitals?
3. How are medications distributed and retrieved for inpatient medication administration in hospitals?
4. How do hospitals differ in the policies and guidance available to support medication administration?

A fifth 'catch-all' question was included:

5. What local initiatives have been implemented to improve any of the following: pharmacy service to inpatients, medication supply and storage on inpatient wards and/or medication administration?

The fifth question was included to identify other systems and processes that potentially have an impact (directly or indirectly) on MAEs. The main systems and resources listed were then refined following further discussion with the two PhD supervisors and the two senior hospital pharmacists before the analytic framework was finalised (table 4.1). This analytic framework formed the basis for the survey questions.

Table 4.1 Overview of analytic framework used to define the scope of the current study and guide development of survey questions.	
Processes	**Resources**
Prescribing and documenting medication administration	Paper or electronic prescribing system
Medication ordering	Pharmacy opening hours
	Ward pharmacist visits
	Pharmacist and/or pharmacy technician for ordering medications
	Out-of hours access to medication supplies ▪ On-call and/or resident pharmacist(s) ▪ Reserve/emergency drug cupboard(s) ▪ Other methods
Medication distribution	Types of medication supplies used ▪ Types of hospital supply (ward stock, one-stop dispensing, inpatient labelled supplies) ▪ Patients' own drugs
	Ward-based medication storage facilities available
Medication administration	Medication storage facilities used during drug rounds
	Local policies and guidance
Other processes that support medication administration	Other resources to support medication administration

4.3.2 Approach to the survey

Respondents

Doctors, nurses, pharmacists, pharmacy technicians and pharmacy assistants are routinely involved in one or more of the processes outlined in table 4.1. Ideally, representatives from each group would have been included to provide information on the specific part or part(s) of the system they were involved with. However, this was deemed impractical, and so pharmacists were chosen because they are routinely involved with and generally have an understanding of all the components in the analytic framework. Specifically, chief pharmacists and senior pharmacists were selected as target respondents for their knowledge of the hospital as a whole, and to ensure the study was conducted with their implicit consent and support. A census of acute and foundation NHS trusts in England was conducted by inviting their chief pharmacists to participate in the study.

Data collection method

Two main approaches to data collection were considered for this study: researcher-administered questionnaire and participant self-administered questionnaire. Each method has its advantages and disadvantages; the choice depends on a number of factors such as complexity and sensitivity of the information required, location of the participants, time and cost limitations. The self-administered approach was chosen for five main reasons: (1) it allowed coverage of a wide geographical area within a relatively short period of time, (2) it gave respondents time to research their answers (if necessary) prior to documenting them, (3) it gave respondents the flexibility to respond when it is convenient for them, (4) potential researcher bias was minimised, and (5) it was relatively low cost compared with researcher-administered questionnaires. Additionally, the self-administered questionnaire approach enabled questions to be presented in the same way to the respondents, which ensured standardisation. The disadvantages of a self-administered questionnaire were that there was little opportunity for participants to obtain clarification from the researchers and that this method was generally associated with a lower response rate than researcher-administered questionnaires. To reduce the risk of respondents misunderstanding the questions, the final questionnaire was developed following extensive fieldwork and pilot studies with 15 hospital pharmacists from four different NHS hospital trusts. In addition, the researcher's contact details were provided to respondents and a number of methods to potentially increase the response rate were used (Edwards et al., 2009); these are described in later sections and in appendix 3.

Number of contacts with respondents

The number of times and methods used to contact respondents depends on the level of responsiveness received. In general, follow-up 'contacts' are standard practice and evidence suggests this increases the odds of response by more than a third (OR 1.35; 95% CI 1.18 -

1.55) (Edwards et al., 2009). Pre-notification has been associated with a higher increase in the odds of response (OR 1.45; 95% CI 1.29 - 1.63)(Edwards et al., 2009), and therefore both methods were used.

4.3.3 Questionnaire development

Developing a questionnaire is an iterative process and almost every aspect of the questionnaire can and should be carefully reviewed (Oppenheim 2000). The aim is to facilitate and encourage the respondents to complete the questionnaire and to do so as accurately as possible. Non-response reduces the effective sample size and can introduce bias. This section explains how the questionnaire was developed and is divided into the following: (1) postal versus on-line questionnaires, (2) type of question and question wording, and (3) methods to increase response rates.

Postal versus on-line questionnaires

The advantages and disadvantages of postal and internet-based questionnaires, including estimates of cost, time, questionnaire design, ease of access to the questionnaire by participants, ease of questionnaire completion by participants, security of information, and data management considerations, were identified and compared (appendix 4). Overall, the postal approach was chosen as it does not require computer or internet access, and questionnaires can be sent to the 'Chief Pharmacist' with relatively low risk of it getting lost compared to email which requires identifying an up to date and correct email address for all 165 chief pharmacists. Furthermore, internet access to the questionnaire may be blocked at some hospitals.

Methods to increase response rate

A Cochrane systematic literature review evaluated 110 different methods to increase response rate from postal questionnaires (Edwards et al., 2009). In total, 481 relevant studies concerning postal questionnaires were included. Methods were meta-analysed in pairs, for example, monetary incentive versus non-monetary incentive, hand-written address versus computer-printed address. Table 4.2 summarises the methods identified for use in this study (represented by group one) and associated odds ratio of their effect on the response rate (over the alternative method in group two).

Table 4.2 Methods used in the current study to potentially increase response rate. Associated odds ratio presented are for the effect of group one over group two. Data from Edwards et al (2009).

Group 1	Group 2	Sample size (number of studies	Odds ratio (95% CI)
More interesting/salient questions	Less interesting/salient questions	2711 (3)	2.00 (1.32-3.04)
Easier questions first	Harder questions first	3182 (2)	1.61 (1.14-2.26)
Postal follow-up including questionnaire	Postal follow-up excluding questionnaire	8619 (11)	1.46 (1.13-1.90)
User friendly	Standard	3540 (1)	1.46 (1.21-1.75)
Pre-contact	No pre-contact	79,651 (47)	1.45 (1.29-1.63)
Follow-up	No follow-up	32,778 (19)	1.35 (1.18-1.55)
Assurance of confidentiality	No assurance	25,000 (1)	1.33 (1.24-1.42)
University sponsor/source	Other	21,628 (14)	1.32 (1.13-1.54)
Hand-written address	Computer printed	5091 (7)	1.25 (1.08-1.45)
Hand-written signature on cover letter	Typed/electronic	15,006 (14)	1.24 (1.08-1.41)
More relevant questions first	More relevant questions last	5817 (1)	1.23 (1.10-1.37)

CI, confidence interval

Type of question and question wording

Due to the fact-finding nature of the study, the questionnaire was designed to consist mainly of closed questions. Closed questions are relatively easy to answer compared to open questions, and require less time from the respondents; thus potentially facilitate

questionnaire completion and therefore increase the response rate. A recent meta-analysis of three studies evaluating the effect of using open versus closed questions found the odds of response were reduced by more than a half when open questions were used (OR 0.31; 95% CI 0.09-1.04), although the results should be interpreted with care as there was significant heterogeneity among the included studies (Edwards et al., 2009).

Other advantages of closed questions are that data can be processed more easily and that quantitative comparisons can be made. Although closed questions may be associated with less risk of non-response (or non-return of questionnaires) compared with open questions, there is still the risk of non-response to specific questions. Ambiguous wording of questions and/or inappropriate answer options may deter the respondent from completing the questionnaire, or elicit incorrect answers; therefore question wording was reviewed in a series of pilot studies with hospital pharmacists. Leading questions and double-barrelled questions were avoided. A category of 'not sure' and/or 'not available' were included in the answer options where appropriate to minimise non-response (Bennett & Ritchie, 1975; Armstrong et al., 1995). The frequency of use of these categories was reviewed during the pilot studies to identify problematic questions which required further revision. In all, the questionnaire was piloted with 15 hospital pharmacists from four NHS trusts. One of the researchers (MM or the other PhD student) sat with each hospital pharmacist as they completed the questionnaire to obtain real-time feedback. This also enabled internal consistency, construct validity, and content validity to be assessed, as MM was familiar with the hospital medication systems used by some of the pharmacists. A number of questions were subsequently rephrased and the following key changes were made: (1) a brief explanation to emphasise the importance of the survey was inserted on the front page of the questionnaire, (2) an option for respondents to select 'one ward' was included in questions where 'all wards', 'most wards', 'some wards', 'no ward' and 'not sure' were standard options, and (3) two open questions were combined: one asked respondents to describe up

to six medication safety related initiatives in their hospital and the other asked about any processes that may affect medication administration errors. The final questionnaire comprised mainly multiple choice questions with tick boxes, a small number of ranking questions and spaces for additional comments (appendix 5).

4.4 Methods

A national cross-sectional postal census of English NHS hospital inpatient medication systems was carried out in July 2011. The survey was conducted in collaboration with another PhD student who explored the use of different electronic prescribing systems in English NHS hospitals. Only data relating to the medication administration-related systems (including inpatient EPMA systems, but not electronic discharge prescribing or other electronic prescribing systems) were presented in this thesis.

4.4.1 The setting, survey population and unit of sample

At the time of the survey, NHS services in England were geographically separated and managed by 10 strategic health authorities (SHAs); each SHA was responsible for the development, provision, and prioritisation of health services for their local area (NHS, 2010). There were multiple acute and/or foundation NHS trusts within each SHA that managed the hospitals within the area. The main difference between acute and foundation NHS trusts was that foundation trusts were recognised independent legal entities (that remain part of the NHS), with more financial and operational freedom than acute trusts.

As each trust (acute or foundation) may comprise more than one hospital, respondents were asked to answer the questionnaire for their main acute hospital only. Hospitals in Mental Health NHS trusts were excluded from this study as processes of drug administration are generally different to that on general medical and surgical inpatient wards (Haw et al., 2007).

Additionally, respondents were asked to exclude intensive care units, maternity wards and mental health wards in their responses as these areas also generally have distinctly different systems to general medical and surgical inpatient wards.

At the time of this study, there were 165 Acute NHS trusts in England (NHS, 2010) across the 10 strategic health authorities: East Midlands, East of England, London, North East, North West, South Central, South East Coast, South West, West Midlands, and Yorkshire and The Humber. All acute and foundation NHS trusts were included (NHS, 2010).

4.4.2 Questionnaire

A pre-piloted questionnaire was developed that included 19 questions relating to medication administration-related systems and processes in hospital inpatient wards. The questions were divided into four sections: (1) hospital demographics, (2) pharmacy service, (3) medication supply and storage on inpatient wards (including the prescribing and medication administration documentation system used), and (4) medication administration, policies, and guidance. Eighteen were closed questions and one was an open question asking the respondent about initiatives that had been implemented in their hospital to improve medication safety.

Of the 18 closed questions, eight had multiple parts that involved the respondent selecting one option from six (“all wards”, “most wards”, “some wards”, “one ward”, “no ward”, or “not sure”). Where relevant, respondents were also asked to identify and rank the three most common system or practice used in their hospital. Three other closed questions had multiple parts; these involved the respondent selecting one option from three (“yes”, “no”, “not sure”) in response to whether a specific administration-related policy guidance was

available. The remaining seven questions asked the respondent to provide hospital and pharmacy demographic information.

4.4.3 Data collection

A pre-notification letter (first contact) was sent to all 165 chief pharmacists in June 2011 (appendix 6). The letter outlined the purpose of the survey, invited them to participate, and explained that a questionnaire will be sent to them within the next two weeks. In July 2011, the questionnaire (appendix 5) was mailed to the chief pharmacists (second contact). A cover letter (appendix 7) and a business-franked addressed envelope for returning the questionnaire was also enclosed to potentially increase the response rate (Edwards et al., 2009). Chief pharmacists were encouraged to delegate questionnaire completion to a senior pharmacist if they preferred, and to return the completed questionnaire by 22 July 2011 (approximately three weeks later). In the questionnaire, respondents were asked to provide their name, job title and contact details if they were willing to be contacted for clarifying responses. Separately, respondents were also asked to indicate if they would be willing to be contacted for the next stage of the research. Respondents were informed on the questionnaire that all data would remain confidential. The researcher's name, telephone and email address was provided in case further information on the study was required by the respondents. A third contact letter was sent in August 2011 to all non-responders thanking them if they had responded recently and reminding them to participate in the survey if they had not already responded (appendix 8). A second copy of the questionnaire and a stamped addressed envelope was also provided. In October 2011, a fourth and final contact was made via email of non-respondents who were known to the research team. An electronic copy of the questionnaire was attached to the email and further responses were invited via email, fax and post.

4.4.4 Data entry and verification

Questionnaire responses were entered verbatim and managed using Microsoft Excel. A random 20% of returned questionnaires entered into the database were verified by another PhD student. Any discrepancies that were identified were reviewed jointly by MM and the other PhD student to confirm, agree, and correct any transcribing errors. Both PhD supervisors were available to discuss any potential problems identified. All completed questionnaires returned by 1 November 2011 were included in the data analysis. One additional completed questionnaire received in December was excluded, and specific questions which were omitted by individual respondents were also excluded from the data analysis for the relevant questions only.

4.4.5 Data analysis

Data were analysed using Microsoft Excel; responses were summarised using descriptive statistics. Percentage response for each question part was calculated; the effective denominator was the total number of usable responses received for the relevant question part. Intra-hospital variations were identified by reviewing responses for questions when 'some' wards were selected; therefore only those questions that asked the respondent to identify the proportion of wards that used a specific system or process within their hospital were included in this part of the analysis. Inter-hospital variations were identified by summarising the responses received for all questions. For questions relating to the proportion of wards that used a specific system or process, the responses for 'all wards' and 'most wards' were combined into the 'majority of wards' in the inter-hospital variation analysis. Responses for 'one ward' and 'no ward' were summarised and reported separately. Further inter-hospital variation was explored by identifying the relevant SHA in which the respondent hospital was located and the use of paper drug charts or EPMA on inpatient wards.

4.4.6 Ethical considerations

The current study was approved by the then University of London School of Pharmacy Research Ethics Committee in June 2011. The local NHS Research Ethics Committee confirmed that research ethics approval was not required as this study met the criteria for service development.

4.5 Results

4.5.1 Overview

Overall, 100 of 165 (61%) questionnaires were returned: 57 (35%) initially and 43 (26%) after follow-up. Respondents were from 59 of 93 (63%) foundation NHS trusts and 41 of 72 (57%) acute NHS trusts. Overall a median of 83% (range 33-93%) of trusts within each of the then 10 SHAs responded (appendix 9); the highest response rate was from Yorkshire and The Humber, and the lowest response rate was from South Central. Median response rate per question part was 97% (range 64-100%) (appendix 10). Characteristics of respondent and non-respondent trusts are summarised in table 4.3; no statistically significant differences were identified.

Table 4.3 Comparison of characteristics between respondents' and non-respondents' trusts.

Trust characteristics	Respondents (n=100 trusts)	Non-respondents* (n = 65 trusts)	Statistical analysis
Median number of acute hospitals in trust (range)	1 (1-5)	1 (1-5)	p=0.08; Mann-Whitney test
Median number of wards at main acute hospital (range)	25 (3 – 60)	23 (1–44)	p=0.12; Mann-Whitney test
Services provided by main acute hospital	Adults (13) or paediatrics (1) only: 14 (14%) Mixed: 86 (86%)	Adults (2) or paediatrics (3) only: 5 (8%) Mixed: 60 (92%)	p = 0.21; Chi-square 1.538

**Data were obtained from the trust websites*

Overall, the majority of hospitals used paper-based prescribing (87% of usable responses), patient bedside medication lockers (92%), ward stock (94%), PODs (89%), and OSD (85%) supplies throughout the hospital (table 4.4). Hospitals varied in the methods used to order medications during pharmacy opening hours, use of drug trolleys to store and transport medicines, use of other methods to transport medicines during drug rounds, and the use of non-OSD supplies. More detailed results are presented separately in the following sections: section 4.5.3 prescribing systems; section 4.5.4 pharmacy services; section 4.5.4 medication storage and supply; section 4.5.5 medication administration related policies and guidance; and section 4.5.6 local initiatives aimed to increase medication safety and/or efficiency.

Table 4.4 An overview of inpatient medication systems in English National health service hospitals.

System*	Number of respondent hospitals (% of usable responses)
Prescribing and medication administration documentation	▪ **Paper or electronic prescribing system (more detail in section 4.5.2)** - 87 (87%) used paper drug charts - 13 (13%) used an EPMA system
Medication ordering	▪ **Pharmacy opening hours and ward visits (section 4.5.3)** ▪ **Ward staff ordered medications† (more detail in section 4.5.3):** - 59 (62%) via the ward pharmacy technician (during ward visit) - 55 (58%) via the ward pharmacist (during ward visit) - 26 (29%) via the ward pharmacist (outside of ward visit) - 24 (26%) by taking drug charts to the pharmacy - 12 (13%) by computer/electronically - 5 (5%) selected 'other': 2 used 'pneumatic tubes', 1 "pharmacy teams are ward based", 1 "bleeping [paging] the sweep pharmacist in the afternoon", and 1 "nurse ordering". ▪ **Availability of pharmacist outside pharmacy opening hours (section 4.5.3)** ▪ **Out of hours access to medication supplies†:** - 97 (97%) borrowed medicines from another ward - 96 (96%) contacted the on-call pharmacist - 89 (89%) used a non-electronic reserve drug cupboard - 39 (39%) borrowed from another patient's hospital supply (same ward) - 11 (11%) used an electronic reserve drug cupboard - 9 (9%) selected 'other': 5 asked the family to bring in PODs, 2 accessed the remote dispensing robot via the on-call pharmacist, 1 stated that medicines were not generally ordered outside of hours, and 1 had a 24-hour hospital pharmacy.
Ward-based medication storage and type of medication supply	▪ **Ward-based medication storage† (more detail in section 4.5.4):** - 91 (92%) used patient bedside medication lockers - 55 (59%) used drug trolleys ▪ **Types of medication supply for inpatient administration†:** - 89 (94%) used ward stock - 85 (89%) used PODs - 82 (85%) used OSD supplies - 46 (50%) used non-OSD supplies - 3 (3%) selected 'other': all 3 used pre-labelled packs
Medication administration processes	▪ **Medication transport during drug rounds† (more detail in section 4.5.5):** - 64 (65%) used drug trolleys - 31 (43%) used medicines cup/oral syringe - 10 (14%) used a tray/basket - 6 (8%) used a temporary trolley (for example, dressing trolley) - 2 (2%) selected 'other': 1 used "prn lockers per bay", 1 "drugs cupboard in 6-bedded bay" ▪ **Policies and guidance (section 4.5.5)**
Other	▪ **Local initiatives aimed to increase medication safety and/or efficiency (section 4.5.6)**

*System that was used on the majority of inpatient medical and surgical wards

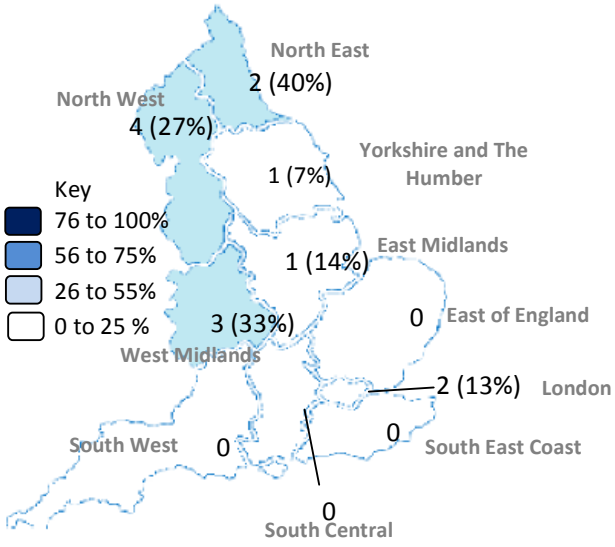
† Percentage total was over 100 as more than one option could be selected by the respondent.

EPMA, electronic prescribing and medication administration; PODs, patients' own drugs; OSD, one-stop dispensing; prn, pro re nata or 'when required'.

4.5.2 Prescribing systems

The 13 hospitals with an EPMA system that were used on the majority of inpatient medical and surgical wards were mainly located in the northern SHAs (figure 1). Exploratory analysis suggests that such EPMA systems were more likely in foundation trusts than acute trusts (13 foundation trusts versus 0 acute trusts, p=0.001, chi-square test).

Figure 4.1 Prevalence of inpatient electronic prescribing and medication administration (EPMA) systems in English NHS trusts. *Number of hospitals that had an EPMA system on the majority of inpatient medical and surgical wards (percentage of trusts within each of the 10 strategic health authorities).*



Of all 100 respondent hospitals, 7 (7%) used an EPMA system on one or some wards, while other wards in the same hospital used a paper-based prescribing system.

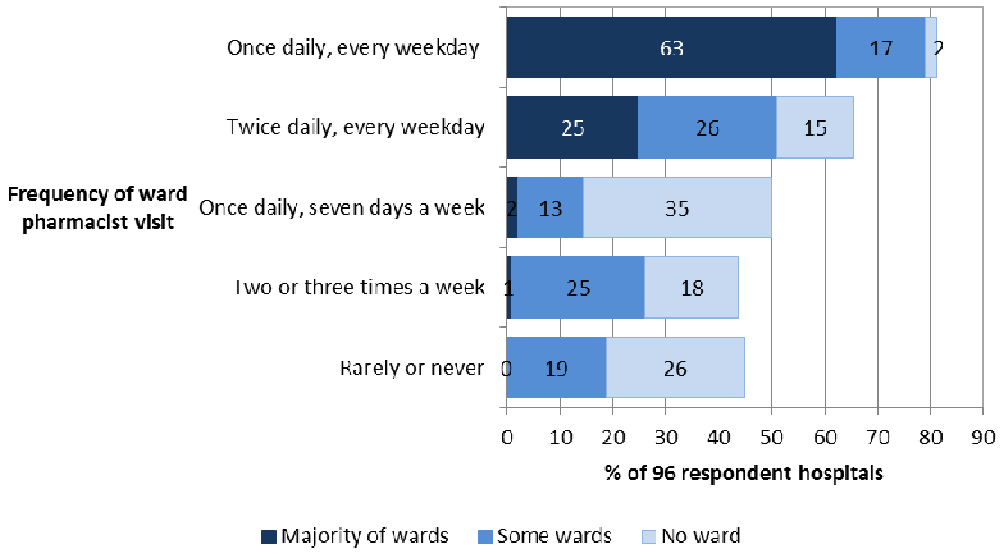
4.5.3 Medication ordering systems

Pharmacy services

One respondent hospital had a pharmacy that was open 24-hours a day. Of the remaining 99 hospitals, the pharmacy was open for a median of 9 hours on weekdays (95% CI 9-10), 5 hours on Saturdays (95% CI 4-5), and 3 hours on Sundays (95% CI 2-4). A total of 96

respondents answered the question about frequency of ward pharmacist visits; the majority of hospitals (86;90%) had at least one daily pharmacist visit on most wards every weekday within the hospital (figure 4.2). Two (2.1%) respondent hospitals selected 'other' as the frequency of ward pharmacist visits on some wards, but no other information was reported.

Figure 4.2 Frequency of ward pharmacist visits in English NHS hospitals. *Totals do not sum to 100% as a number of respondents selected answers that indicated 'majority of wards' for a particular option and therefore the remaining options were not applicable.*



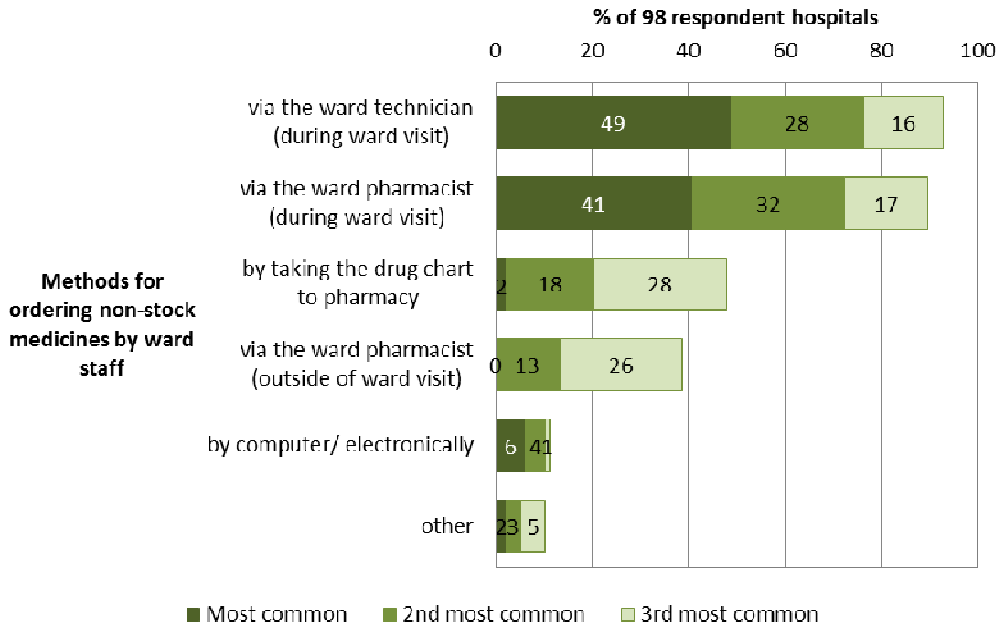
In all, 90 (90%) respondent hospitals had a non-resident on-call pharmacist, 9 (9%) had a resident on-call pharmacist, and 1 (1%) had neither because there was a 24-hour pharmacy service available. There was no significant difference in hospital size between those with an on-call pharmacist (mean 25 wards per hospital, 95% CI 23-28) and those with a resident pharmacist (mean 33 wards per hospital, 95% CI 23-43). There was also no significant difference in the type of NHS trust (acute or foundation) between those with an on-call pharmacist (42% acute, 58% foundation) and those with a resident pharmacist (22% acute, 78% foundation) ($p = 0.42$, chi-square with Yates' correction).

Methods used to order non-stock medications for inpatient use

Overall, a median of three methods (range 1 to 6) were used in respondent hospitals to obtain medicines outside of pharmacy opening hours. An overview of medication ordering methods used by respondent hospitals is presented in table 4.4. As more than one method could be used in each hospital, respondents were also asked to rank the three methods that were most common (figure 4.3). Overall, ordering medications via the ward pharmacy technician was the most common method (48; 49% of respondent hospitals).

A sub-analysis of 14 (15%) hospitals that had both a ward pharmacist and pharmacy technician on the majority of wards revealed that the most common method was ordering medicines via the 'ward pharmacist during their ward visit' (6; 43%), followed by the 'ward technician during their ward visit' (5; 36%), and 1 (8%) each of the following: 'taking the drug chart to pharmacy' as the most common method, via the 'computer/electronically', and "other – pharmacy teams are ward-based".

Figure 4.3 Methods used to order non-stock medicines by ward staff in English NHS hospitals. *Totals do not sum to 100% as respondents were asked to rank the three most common methods rather than rank all methods.*

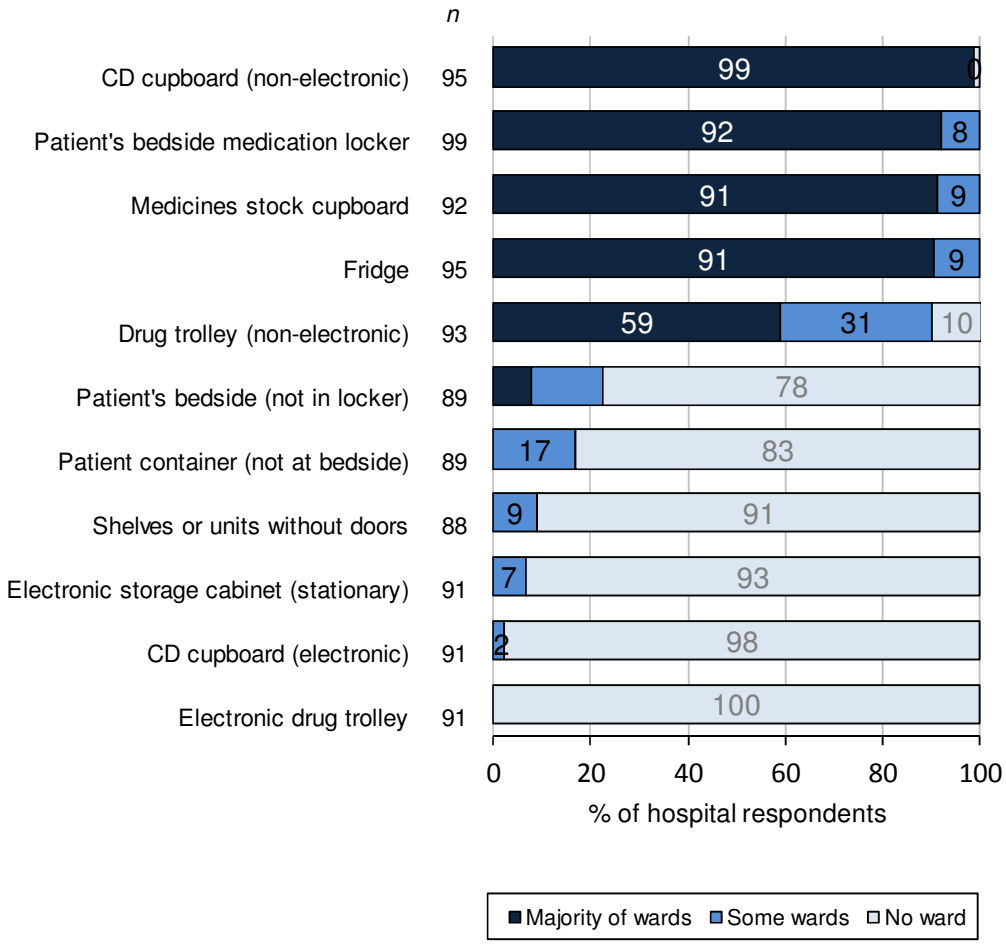


4.5.4 Ward-based medication storage and types of medication supplies

Ward-based medication storage

Overall, four of 11 types of medication storage facility were available on the majority of wards in respondents' hospitals: a non-electronic CD cupboard, patient bedside medication lockers, medicines stock cupboards, and a fridge (figure 4.4).

Figure 4.4 Availability of different ward-based medication storage facilities on wards in English NHS hospitals. *n represents total number of respondent hospitals for each medication storage facility (effective denominator). CD: controlled drugs.*



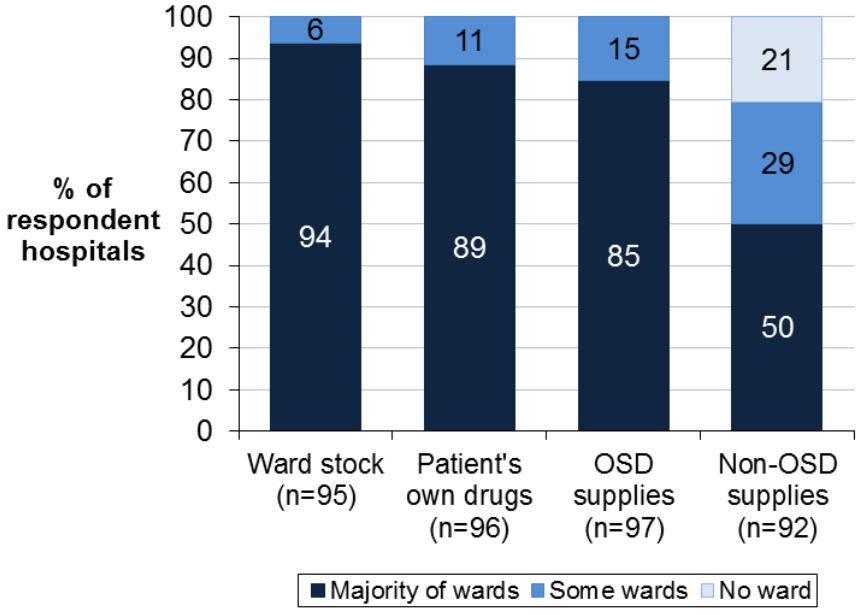
Use of drug trolleys was associated with the most intra-hospital variation; 31% of respondent hospitals used these on some wards only. Exploratory analysis according to SHA suggests drug trolleys remain widely used in the South Central (100% of 3 hospitals) and London SHAs

(86% of 7 hospitals), and least used in the North West (27% of 11 hospitals) and East Midlands SHAs (29% of 7 hospitals) (appendix 11). When asked about the most common medication storage used to retrieve medications from at the time of administration, 71 (72%) respondents reported patient bedside medication locker, 15 (16%) reported a drug trolley, 10 (11%) reported medicines cupboard, and 2 (2%) reported patient's bedside table or belongings.

Types of medication supplies

In general, the majority of respondent hospitals used ward-stock, OSD supplies, and PODs on the majority of wards (figure 4.5).

Figure 4.5 Types of medication supply used for inpatient medication administration in English NHS hospitals. *n represents the number of complete responses for each type of medication supply.*



Relatively greater inter- and intra-hospital variation was reported for non-OSD supplies; 50% used these on the majority of wards, 29% on some wards, and 21% did not use them on any ward. Exploratory analysis of non-OSD use between SHAs suggests non-OSD were widely used in South Central SHA (100% of 2 hospitals), and least used in West Midlands SHA (22%

of 9 hospitals) (appendix 12). Three respondents additionally selected 'other' and specified the use of pre-labelled packs (medicines that have been labelled with standard dosage instructions but not with the patient's name) for inpatient use on wards in their hospital. These pre-labelled packs were referred to as 'PLPs' (pre-labelled packs), 'TTO packs' ('to take out'), or more generically as 'prepacks'. When asked about the most common type of medication supply used on inpatient wards, 31 (34%) respondents reported PODs, 31 (34%) reported OSDs, 27 (30%) reported ward-stock, and 1 (1%) reported non-OSD supplies.

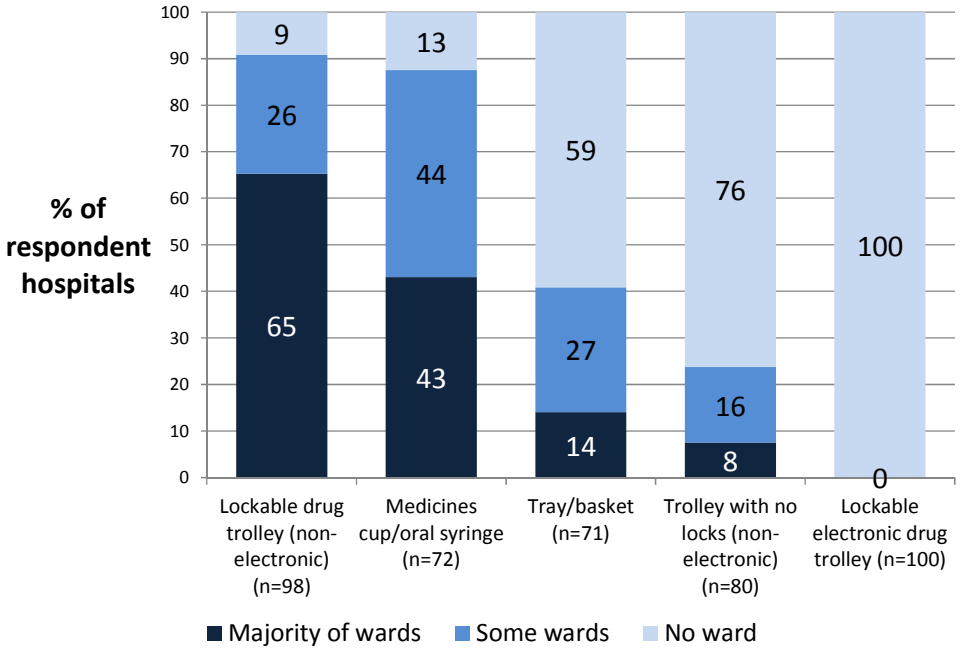
4.5.5 Medication administration process

Of 99 usable responses, all respondents reported the use of regularly scheduled drug rounds on the majority of wards in their hospital.

Methods used to transport oral medicines to patients

There were inter- and intra-hospital variations in the methods used to transport medicines to patients during drug rounds, including the use of a drug trolley (figure 4.6). In addition, three respondents selected 'other' methods to transport oral medicines: "prn [when required] lockers per bay" on the majority of wards in one hospital, "drugs cupboard in 6-bedded bay" on some wards in one hospital, and "individual items carried by nurse (in hands)" on some wards in one hospital.

Figure 4.6 Methods used to transport oral medicines during drug rounds in English NHS hospitals. *n represents the number of complete responses for each method used to transport oral medications to patients.*



Where oral doses were most commonly retrieved from

When asked which storage location the respondent thought was most commonly used to retrieve medications from during drug rounds, 72% (from 98 usable responses) of respondents stated patient bedside medication lockers, 16% stated drug trolleys and 11% stated medicines stock cupboard.

Double-checking medications

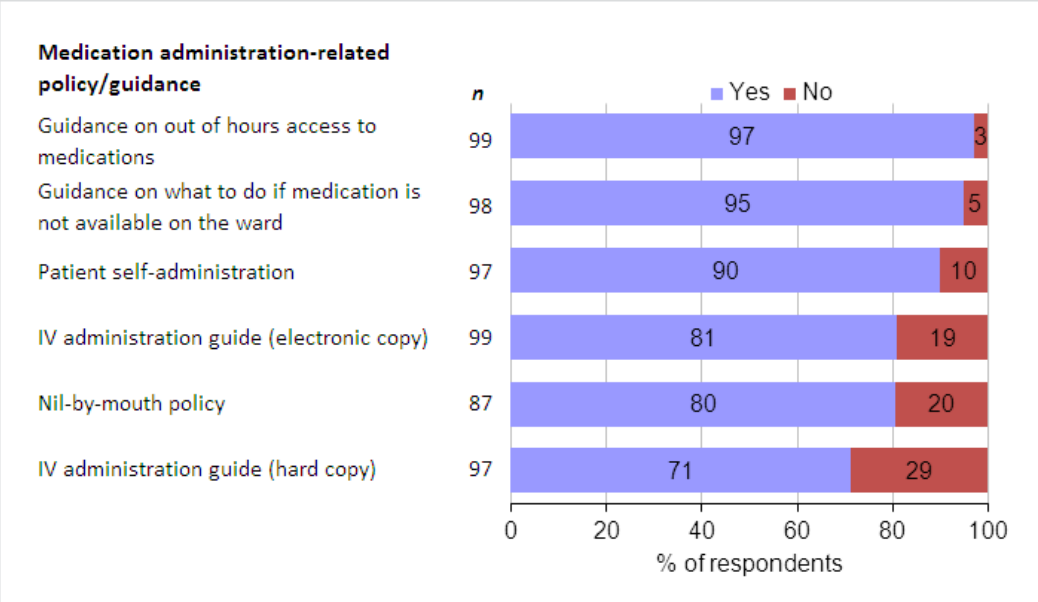
Respondents were asked if double-checking prior to administration was required for five specific groups of drugs: 82 (85% of 97 usable responses) stated 'yes' for IV medications, 63 (65%) for IV fluids, 94 (97%) for parenteral chemotherapy, 73 (75%) for oral chemotherapy, and 81 (83%) for paediatric doses. Double-checking of CDs was excluded from this question as this is a legal requirement in the UK. When asked which other specific drugs required double-checking prior to administration, 37 (58% of 64 usable responses) respondents reported 15 types of drugs (table 4.5). The route of administration of named drugs was not specified by the respondents. Overall, insulin was the most commonly named drug that required a double-check prior to administration in respondents' hospitals (16; 25%).

Table 4.5 Named drugs and groups of drugs that were double-checked prior to administration	
Drug name/group	Number of respondent hospitals
Double checking of specific drugs required but names of drugs not provided	27 (42)
Insulin	16 (25)
Heparin	7 (11)
Complex preparations	6 (9)
Potassium	5 (8)
Epidurals	3 (5)
Infusion devices	2 (3)
Intrathecal administration	2 (3)
Oral methotrexate	2 (3)
Saline flushes	2 (3)
Therapeutic low molecular weight heparins	2 (3)
Trial drugs	2 (3)
High risk intravenous drugs	1 (2)
Intravenous immunoglobulin	1 (2)
Midazolam	1 (2)
Paediatric doses requiring calculations	1 (2)
Total percentage is over 100% as some respondent hospitals had more than one drug-specific double-checking policy in place.	

Other medication-related policies, guidance, and practices

Six specific medication-related policies and guidance were listed in the questionnaire and respondents were asked if each were available in their hospital (figure 4.7). The majority of respondent hospitals had all the policies and guidance listed. Guidance for administering IV medications was more commonly available electronically than on paper. One respondent additionally reported that their hospital had an 'opt out patient self-administration scheme'.

Figure 4.7 Availability of different medication administration-related policies and guidance in English NHS hospitals. *n value represents the number of complete responses.*



A total of 56 (59% of 95 usable responses) respondents reported the use of a 'do not disturb overall/sash' by nursing staff routinely during medication administration on at least one ward in their hospital. Administration of medications by a patient's carer (for example, parent, spouse) was routinely practised on at least one ward in 24 (27% of 89 usable responses) of respondents' hospital; of these, 23 were in mixed adult and paediatric hospitals and 1 was in an adult only hospital.

4.5.6 Local initiatives which aimed to improve medication supply, storage, and/or administration

Finally, respondents were invited to provide additional information on any initiatives that had been implemented in their hospital to improve either the pharmacy service to inpatients, medication supply and storage on inpatient wards, and/or medication administration. In all, seven main strategies were described by 32 respondents (table 4.6). Additionally, two other

respondents reported on lack of investment, high workload with few staff and multiple vacancies as barriers for developing pharmacy services further in their hospital.

Table 4.6 Reported local initiatives used in English National Health Service hospitals to improve medication supply, storage, and/or administration.

Local initiative	Number of hospitals	Examples
Extensive ward pharmacy technician and/or pharmacy assistant service	10	Technician discharge transcribing service, and trial of technician medication administration
Near-patient dispensing	9	Use of mobile dispensing units, satellite dispensary, and prepacks
Extended pharmacy services to wards	7	Increased frequency of ward pharmacy visits, increased pharmacy opening hours, and provision of pharmacy service to wards on weekends
Use of OSD and PODs	6	(see section 4.5.4 for percentage of hospitals that use OSD supplies and PODs)
Self-administration schemes	4	Specific self-administration scheme for patients with Parkinson's disease and separately for maternity units, and an 'opt-out' patient self-administration scheme
Technology	3	EPMA, automated medication storage cabinets (for example, Omnicell®), an electronic discharge prescribing system, and an electronic prescription tracking system
Quarterly medication storage review on wards	2	
Other	8	Director/matron walkabouts with medicines checks on wards to identify potential medication problems and provide immediate feedback to ward staff, fast-track medication request system, pneumatic tube system, double-checking policy for IV medicines, non-OSD supplies being additionally labelled with "inpatient supply only" to remind staff not to issue these to patients on discharge, standard operating procedures for nurses on specific administration processes, target turnaround times for inpatient supply, and changed order of tasks during drug administrations with IVs administered first followed by medicines on the critical list then other non-IV medications.

EPMA, electronic prescribing and medication administration; IV, intravenous; OSD, one-stop dispensing; POD, patients' own drugs.

The most frequently reported local initiatives were based on expanding ward pharmacy services and near-patient dispensing.

4.6 Discussion

4.6.1 Main findings

Overall, the extent of use of a number of core medication systems in English NHS hospitals was identified. The majority of hospitals used paper-based prescribing (87%), patient bedside medication lockers (92%), ward stock (94%), PODs (89%), and OSD supplies (85%) in the majority of inpatient wards. However, hospitals varied in the methods that were primarily used to order medications during pharmacy opening hours; variations were mainly attributed to ordering medicines via the ward pharmacist and/or pharmacy technician. There were also inter- and intra-hospital variations in practices that were once standard prior to the national introduction of PODs, OSD, and patient bedside medication lockers; these include use of drug trolleys to store and transport medicines, use of other methods to transport medicines during drug rounds, and the use of non-OSD supplies for inpatient use. Such variations suggest hospitals have implemented the national initiatives in different ways. Exploratory analysis by SHA suggests that there are some geographical differences between hospitals that use drug trolleys and non-OSD supplies, but statistical significance was not tested due to the risk of a type 1 error that are associated multiple comparisons.

In addition, the prevalence of a number of medication administration related policies, guidance and double-checking practices was also identified. In particular, 85% of hospitals had a double-checking policy for IV administrations and 58% for specific drugs or groups of drugs. The widely advocated “do not disturb” tabard/overall for reducing interruptions during drug rounds was used routinely on at least one ward in 59% of hospitals, and administration of medications by a patient’s carer (for example, parent and/or spouse) in 27% of hospitals. Across English NHS hospitals, current efforts to improve safety and efficiency of medication supply, storage and administration appear to concentrate on extending ward and clinical pharmacy services.

4.6.2 Comparisons with previous research

This is the first national survey of medication systems used in English NHS hospitals. Previous surveys that involved studying medication systems were primarily pharmacy-specific, did not include ward-based medication systems in use or were not specific to the UK (Cotter et al., 1994; Doloresco & Vermeulen, 2009; Pedersen et al., 2012; Frontini et al., 2012) and therefore not all aspects of our survey findings can be compared with the literature. Comparison of our pharmacy-specific findings with those from the UK clinical pharmacy survey conducted in 1992 (Cotter et al., 1994), suggest that more hospital pharmacies are now providing a weekend service: 74% of UK hospitals were open on Saturdays in 1992 versus 90% of English hospitals in 2011, 10% of UK hospitals were open on Sundays in 1992 versus 74% of English hospitals in 2011. However, the percentage of hospitals that provide a resident on-call pharmacy service (9% of UK hospitals in 1992 versus 9% of English hospitals in 2011) and non-resident on-call pharmacy service (88% of UK hospitals in 1992 versus 90% of English hospitals in 2011) remain the same.

Another aspect of our survey for which previous data was available was the prevalence of technological systems used in the US. Research suggests electronic systems for prescribing, documenting administration, and storing medications are more widespread in US hospitals than in England (Pedersen et al., 2011; 2012). For example, 67% of US hospitals have an electronic medication administration record (MAR) compared to 13% in England with an EPMA system, and 89% of US hospitals have electronic medication storage facilities compared to 7% in England. However, unlike the combined inpatient prescribing and medication administration systems used in the UK (paper-based or EPMA), inpatient prescribing systems are generally separate from the medication administration record system in the US. This may partly explain the apparent difference in uptake of technological systems; the current 'multi-purpose' EPMA systems used in the UK may be more challenging for technological developers than the 'single purpose' systems used elsewhere.

4.6.3 Implications for practice

Identifying system similarities across the NHS provides an important context for those seeking to develop and prioritise systems based interventions to increase medication safety. However, identifying and exploring system differences between hospitals enable advantages and disadvantages of the medication systems to be better understood, and therefore inform future developments in their design, application, and/or implementation. Two of the variations that we identified in medication systems were unexpected: (1) medication storage and transport (specifically relating to the use or not of drug trolleys), and (2) types of medication supply (specifically relating to the use or not of non-OSD supplies).

Medication storage

Hospitals varied in whether or not drug trolleys were used, and in the proportion of wards in which drug trolleys were used. Inter- and intra-hospital variations in drug trolley use are difficult to interpret as drug trolleys serve the two functions of storage and transport. The introduction of patient bedside medication lockers around 2001 was not specifically intended to eliminate the use of drug trolleys as bedside medication lockers could not replace the 'transport' functionality. However the survey results revealed drug trolley use was much lower than expected; drug trolleys were previously reported as a standard component of medication administration during drug rounds in UK hospital inpatient wards (Dean et al., 1995; Brock & Franklin, 2007). Data from this survey also suggest some hospitals are using other devices to transport medications on the majority of wards, for example, a tray or a basket, with or without a dressing trolley to transport medications to patient's bedside during oral drug rounds. These alternative solutions may have arisen from the need to transfer medications from stock cabinets to the patient's bedside due to insufficient medication supply in the patient's bedside medication locker. Storing all the medications that are prescribed for the patient may not be practical for a number of reasons: (1) there may be insufficient space to physically store all the medications that the patient is on, (2) it

may be inefficient to store commonly used medicines in each patient's bedside medication locker (costs for small pack sizes are often higher than for larger pack sizes). The implication is that there may still be a role for re-introducing lockable drug trolleys or some sort of lockable and/or wheelable device for transporting medications on some wards.

Types of medication supplies

Findings from the survey suggest only 50% of hospitals now use non-OSD inpatient supplies compared with what would have been standard prior to the introduction of OSD. *"[By April 2002] all hospitals will have a 'one stop dispensing/dispensing for discharge' schemes".* This was one of the milestones set by the Department of Health in the Medicines and Older People report (Department of Health, 2001; p27), which was then taken further by the Audit Commission (2001) to promote original pack dispensing and patient self-administration schemes, alongside implementation of patient bedside medication lockers. However, it was unclear from these documents whether or not traditional 'non-OSD' inpatient labelled supplies still had a role in hospitals. Ten years on and results from the present survey revealed OSD supplies were used in all hospitals, and on the majority of inpatient wards in 85% of hospitals. This high up-take may indicate that the potential benefits of OSD have translated into real benefits in practice; this may also explain why only 50% hospitals continue to use non-OSD inpatient labelled supplies on the majority of wards and 21% hospitals do not use these at all. However, further research is required to substantiate these speculations. Both locally and nationally, we now have more experience with the use of OSD. Thus, it would be useful to explore the rationale behind the respondent hospitals that have stopped using non-OSD inpatient labelled. Simplifying the types of hospital medication supplies used may offer additional benefits for medication safety, reduce the number of re-supplies, reduce time spent re-labelling non-OSD inpatient supplies, and therefore potentially reduce costs. However, the disadvantages would also need to be considered such as how to

manage patients that use a medicines compliance aid, when supplying OSD may increase the risk of the patient going home without their compliance aid.

4.6.4 Strengths and limitations of the current study

A strength of the present study was the census approach, which enabled an overview of systems and processes to support medication administration across English NHS hospitals to be identified. The response rate in this study (61% of hospitals) was higher than that which was previously reported for other similar surveys in the US (40% and 29% of hospitals; Pedersen 2012;2011, respectively), and also than the UK-specific response rate (35%) in the European survey by Frontini et al (2012). Responses in the present study also represented a range of hospital sizes from both acute and foundation NHS trusts. Thus, the findings may facilitate prioritisation and development of potential systems-based interventions to reduce MAEs. Furthermore, the inclusion of medication administration-related policies in the survey provided additional insight into the prevalence of specific organisational support for medication administration in hospitals. However, there were also a number of study limitations. First, the present survey was focused on English NHS hospitals; therefore, the findings cannot be extrapolated to the NHS in Wales, Scotland, or Northern Ireland. Second, specific parts of the questions were not completed by all respondents; however, these were relatively infrequent and therefore unlikely to have affected interpretation of the results. Third, a small number of questions asked the respondents to describe use of the system 'in their experience'; responses for these subjective questions should therefore be interpreted with care. Lastly, a number other technologies to support medication administration were not included in the survey, for example, use of BCMA and 'smart' infusion pumps.

4.6.5 Future research

Having identified and described a number of variations in the hospital medication systems used in English NHS hospitals, further research is needed to explore the effects of different medication systems and processes on MAEs and to develop potential NHS-wide interventions to reduce MAEs. Based on the survey findings, the medication storage and distribution system was identified as a particular area of interest for this thesis and a study was therefore conducted to take this research further. Chapter five describes an observational study that focused on medication storage and dose retrieval during non-IV drug rounds to better understand how different medication storage facilities are used in practice, and which, if any specific medication storage facilities offer safety and efficiency benefits over others.

In addition, findings from the survey may provide a useful starting point for future surveys to monitor the use of hospital medication systems and processes. The potential expansion of EPMA implementation in the future will most probably lead to substantial changes. Thus, monitoring the use of different hospital medication systems would not only facilitate prioritisation of potential NHS-wide interventions to increase medication safety, but also provide an indicator of the pace of change in the NHS which may be useful to policy makers.

4.7 Conclusion

Prior to the present survey, the extent of use of many specific systems and processes to support medication administration in NHS hospitals was unknown. Findings from the current survey have revealed the prevalence of many such systems and processes, including the extent of inter- and intra-hospital systems variations that exist. Such variations suggest that hospitals have implemented core medication systems in different ways, particularly in relation to the use of ward-based medication storage and transport systems and the use of double-checking policies for specific drugs or groups of drugs. Further research is needed to

explore the implications of such variations, investigate their contribution to MAEs, and to develop potential interventions to reduce MAEs that are applicable across the NHS. Thus, the next chapter describes a study to investigate variation in ward-based medication storage in more detail and their potential effects on medication retrieval across three acute hospitals of one NHS trust.

Chapter 5. Exploration of variations in ward-based medication storage and their potential effects on dose retrieval in one acute NHS trust

5.1 Introduction

In the systematic literature review in chapter three (M^{c}Leod et al., 2013), non-therapeutic dose omissions were consistently found in observational studies to be the most common subcategory of MAEs in UK NHS hospitals; omission due to drug unavailability accounted for over half of omissions in non-IV doses. In chapter four, the national survey identified variation in the types of ward-based medication storage systems used both within and between hospitals. This chapter now describes variations in current practices of ward-based medication storage and retrieval in one large acute NHS trust, and explores how medication storage may affect the success and timeliness of dose retrieval during non-IV drug rounds.

5.2 Background

Since the introduction of patients' bedside medication lockers around the year 2000 (Department of Health, 2000b; Audit Commission, 2001), there has been a shift in the number and types of medication storage facilities used in English hospital wards (chapter four), with little research investigating their impact on medication administration.

One partially-controlled before and after study investigated the effects of implementing patient bedside medication lockers and PODs on MAEs (Dean & Barber, 2000). The study involved observation of 6,067 OEs on one general medical and one general surgical ward of an English NHS hospital. Using robust observation methods and clear definitions, the researchers found no significant difference in overall MAE rates between wards with bedside medication lockers and wards without. However, sub-analysis of the data suggested that there may be differences in the MAE subcategories that occur. In general, there were fewer omissions due to nurses not being able to find the medication when bedside medication lockers were available than when they were not. However, more 'wrong dose' errors were observed with bedside medication lockers than without. Despite insufficient sample in the sub-analysis for statistical significance to be assessed, this study highlighted the potential effects of different medication storage on specific subcategories of MAES.

More recently, a study in an Northern Irish hospital also investigated the potential effects of implementing patient bedside medication lockers on MAEs (Hogg et al., 2012). The study involved observation of 4,211 doses across two general medical and two general surgical wards of two hospitals. The researchers found a reduction in overall MAE rate (including wrong time errors) post-implementation of patient bedside medication lockers. Dose omissions were the most common MAE subtype observed which were also reduced post-intervention. However, several key information were not reported which limited interpretability of the findings: the number of MAEs that could be associated with each OE, the number of observers collecting data, how data collection was standardised between observers, whether inter-observer reliability was assessed, what statistical tests were used for data analysis, and whether or not drug trolleys were continued to be used post-intervention. In addition, it was unclear how the pharmacy technician replenished the drug trolley and bedside medication lockers during the study period, and if changes in how medications were supplied might have also affected the reported error rates.

While previous research in this area has generally focused on the effects of introducing patients' bedside medication lockers on MAEs, none have examined how the combination of different types of medication storage facilities may also affect MAE rates, particularly dose omissions. Survey data suggest the use of patient bedside medication lockers are now widespread in English NHS hospitals, but the additional use of a conventional drug trolley and/or other types of medication storage was variable (chapter four). Furthermore, availability of a particular type of storage facility on the same wards does not necessarily mean it will be used in the same way. A study by Dean et al., (1998) of 1,002 observed doses, on two general medical wards, identified differences in where nurses stored individually dispensed preparations; some nurses stored these in the drug trolley while others kept these at the patient's bedside. According to the researchers, "this sometimes resulted in the omission of medication if the nurse could not find the drugs where he or she expected to find them". In addition, difficulties locating the drugs would conceivably increase the nurse's time on the drug round and result in a delay in administering any subsequent doses.

Nationally, the problem of omitted and delayed doses has become one of the medication safety priorities for the NHS (National Patient Safety Agency, 2010a). A recent review of medication incidents submitted to the NHS NRLS found 'omitted and delayed medicine' to be the most common error category reported by health care professions; accounting for 16% of over half a million incidents in England and Wales (Cousins et al., 2012). While the majority of these did not cause patient harm, earlier figures from a subset of the same data found omissions and delays of some time-critical medicines were associated with 27 deaths and 68 cases of severe harm (National Patient Safety Agency, 2010b).

Locally, in one large acute NHS trust, informal feedback from staff suggested there were a number of problems associated with the use of patient bedside medication lockers. Reported problems include the following: there was often insufficient space in the bedside

medication locker to store medicines, not all doses were always found, and the nurse may end up walking back and forth to the stock cupboard or drug trolley to retrieve a dose. In addition, keys were not always available or did not work very well, and there was generally little space around the bedside medication locker to place the drug chart. Consequently, it was suspected that the current system was no longer fit for purpose. Concerns were raised about dose omissions due to difficulties finding medicines on the ward, and drug rounds were perceived as becoming excessively time consuming. However, it was unclear what the current medication storage practice was within the trust. Inpatient wards were located across three large hospital sites. These hospitals were previously from two different acute NHS trusts prior to their merger in 2007 and therefore practices may have evolved differently. Thus, the present study to investigate variations in ward-based medication storage and dose retrieval was conducted.

5.2 Aims and objectives

The aims of this study were to describe current practices of medication storage and retrieval during non-IV drug rounds on inpatient wards of one NHS trust, and to explore potential effects of different medication storage systems on successful and timely dose administrations. Specifically, the objectives were to:

(1) Describe the number and types of ward-based medication storage facilities available on general medical and surgical wards within one trust;

(2) Identify the successful dose retrieval rate and the types of medication storage locations searched in during non-IV drug rounds;

(3) Document the timeliness of medication administration on non-IV drug rounds;

(4) Document the number of physical steps taken by nursing staff to complete drug rounds;

(5) Explore the relationship between different ward-based medication storage systems used and the outcome measures (2) to (4) above.

5.3 Methods

5.3.1 Setting

The study was conducted in three acute hospitals comprising 450, 344, and 441 beds respectively, and one 83-bed specialist women's and children's hospital. The four hospitals were located on three separate sites (A to C) of one large acute NHS trust; site B additionally included the specialist hospital. Clinical pharmacy services and medication supplies for both hospitals at site B were provided by the same pharmacy department. All NHS medical and surgical wards were included. Intensive care, high dependency, accident and emergency, paediatrics and neonatal wards were excluded as medications were generally not administered at pre-specified drug round times in these areas. To minimise the risk of infection to immune-compromised patients, all haematology, oncology and HIV wards were also excluded. The inpatient specialties included at site A were therefore acute medicine, medicine for the elderly, gastroenterology, respiratory, rheumatology, neurology, stroke, gastrointestinal surgery, neurosurgery, plastic surgery, and orthopaedic surgery. At site B, included wards were acute medicine, cardiology, cardiothoracic surgery, rheumatology, endocrinology, hepatobiliary surgery, gynaecology, obstetrics, and renal medicine. At site C, included wards were acute medicine, medicine for the elderly, vascular, stroke, gynaecology, and obstetrics.

Across the trust, nursing staff generally administered medications from paper drug charts during four scheduled drug rounds each day. The pre-printed drug administration times on drug charts were 0800, 1200, 1800 and 2200 hours. Each ward held a selection of stock medications that were commonly prescribed for the relevant patient population. Non-ward-

stock medications for specific patients were ordered from the hospital pharmacy as OSD or non-OSD inpatient supplies. The trust had a typical OSD policy where four-week supplies of long-term medications were issued from pharmacy, labelled with administration information for the patient. These could be used for inpatient administration by nursing staff, self-administration by the patient, and/or to expedite medication supply at discharge. For medications that were unlikely to be continued on discharge, pharmacy supplied sufficient non-OSD medication for the anticipated inpatient stay, labelled specifically for the patient but without instructions for use. Additionally, the use of PODs was encouraged. Most patient-specific medications were stored in dedicated bedside medication lockers; trust policy permitted insulin, inhalers, creams and ointments to be kept at the bedside outside the bedside medication locker.

5.3.2 Data collection

Observation training and standardisation

Data were collected with the assistance of three pharmacy undergraduate students over four weeks in March 2012 using standardised observational methods and data collection forms (appendix 13). MM coordinated and supervised data collection. Each student observer was given training on conducting observations which comprised: (1) group briefing sessions on the study, practicalities of observing drug rounds, trust policies and guidance relating to drug administration, (2) several ward visits with a trust pharmacist to become familiar with general hospital practice on the ward and ward layout, (3) shadowing a number of different nurses on their drug rounds, and (4) conducting pilot observations on a number of wards. In addition, MM held weekly meetings with all student observers to consolidate observation training, resolve any queries prior to starting data collection and to establish a routine of regular feedback and discussion following observations. The weekly meetings continued throughout the remainder of the study period to maximise standardisation in data collection

between all three observers. The study was not specifically designed to identify all MAEs, however in case an MAE was identified that may cause patient harm; observers were taught in advance how to intervene in a discreet and non-judgemental manner.

Drug rounds and nurse participants observed

Each observer collected data at one hospital site. One morning drug round (8am) and one lunchtime drug round (12pm) was observed on each included ward. As each nurse generally administered drugs to the patients he or she was looking after, more than one drug round sometimes occurred at each scheduled drug round time; only one nurse could therefore be observed on each occasion. Observers sketched the ward layout and location of patients on the drug round observed. No patient or nurse identifiable information was collected. However, data on the 'band' and level of experience of each nurse were documented to assess comparability of nursing staff observed between sites. In general, the NHS 'Agenda for Change' bands were used within the trust to differentiate levels of seniority between nursing staff rather than job titles. Newly qualified nurses usually started at band 5, senior nurses were generally band 6, and band 7s were advanced nurse leaders and/or ward sisters.

Ward-based medication storage locations

The types of medication storage facilities available, and the locations searched for each dose were documented. Based on pilot observations, medication storage locations were categorised into one of nine mutually exclusive categories: (1) patient's bedside medication locker, (2) patient's bedside area (for example, bedside table or cabinet but not in bedside medication locker), (3) a conventional drug trolley, (4) a container with or without a temporary trolley, (5) stock cupboard, (6) fridge, (7) controlled drugs cabinet, (8) 'other', and (9) dose 'not found'. Observers documented a brief description of any 'other' medication storage locations. Doses were categorised as not found if the nurse could not find the dose during the drug round observed. Photographs of different medication storage facilities were

taken to illustrate relevant practice after obtaining verbal permission from the nurse in charge.

Duration of drug rounds

The time taken to complete each drug round was documented. Timing started when the nurse picked up the first drug chart or indicated to the observer that they were starting the drug round (whichever happened first) and finished when the nurse had completed administration and/or documentation of the last dose for the drug round and indicated to the observer that they had completed the drug round.

Physical steps during drug rounds

Nurses were asked to wear a pedometer (Yamax Digi-Walker SW-200) during the observed drug round. This spring-levered pedometer was chosen as it is not influenced by the variety of walking paces that are likely to occur during drug rounds, unlike more advanced accelerometer-based pedometers which calculate the number of steps based on acceleration due to movement over time (Corder et al., 2007). This latter type are designed for sports use and filter the first few steps detected to avoid measuring 'incidental movements'; they were therefore considered unsuitable for the present study.

Other types of data collected

In addition, observers documented whether or not the drug chart was misplaced or missing at the time it was needed. This was not initially included but was added to the data collection form following pilot observations. A drug chart was considered to be 'misplaced' if it was not found in its usual location for the ward, for example, in the bedside folder at the end of the bed or in a centralised folder at the drug trolley (but was subsequently located). A drug chart was documented as 'missing' if it was not found at all by the end of the drug round period observed.

Finally, nurses were given the opportunity to provide feedback at the end of the drug round. The observer asked the nurse: (1) would you consider that to be a typical drug round? (2) How did you find being observed?

5.3.3 Inter-observer reliability

MM observed two drug rounds with each student observer and collected data independently to assess inter-observer reliability: one round prior to starting data collection to standardise the method of data collection, and one round two weeks into the data collection period to help ensure that data collection remained consistent. The kappa-statistic was calculated for the number and types of locations searched for each dose during the drug rounds observed by MM (<0.4 poor agreement, 0.4 to 0.75 fair to good agreement, and >0.75 excellent agreement) (Fleiss, 1981).

5.3.4 Data analysis

All data were summarised using descriptive statistics and compared between sites. The successful dose retrieval rate and the proportion of attempted doses retrieved from different locations were compared between hospital sites using a chi-square test. Significant differences were additionally analysed post-hoc using the Marasquilo procedure (Levine, 1946) to determine which specific sites were different. All data for the three sites were then pooled and grouped according to the type of medication storage system used during the drug rounds. These groups were used to explore potential effects of different types of medication storage systems on successful dose retrieval rates, time taken per attempted dose administration, and number of steps taken per attempted dose administration. Descriptive statistics including 95% CI were calculated to explore potential differences between systems.

5.3.5 Calculation of successful dose retrieval rate

The number of doses that were successfully retrieved and given to patients (including leaving a dose at the bedside for subsequent administration) was documented. The success rate of medication retrieval was calculated as follows:

$$\textit{Successful dose retrieval rate} = \frac{\textit{sum of all doses retrieved}}{\textit{Sum of all attempted dose administrations}} \times 100\%$$

The denominator was the sum of all attempted dose administrations, defined as a dose which was searched for in at least one location, irrespective of whether or not it was subsequently retrieved and administered. All attempted dose administrations observed during the non-IV drug round were documented, including nutritional supplements, 'when-required', 'once-only' doses, and any doses for which the observer intervened. Any IV doses that were administered during the non-IV drug round were also included as these would affect the parameters being measured; those administered outside the non-IV drug round were excluded. Doses that were omitted without any attempt to administer them were also excluded.

5.3.6 Study approval and participant consent

This study met the criteria for service evaluation and therefore did not require NHS ethics approval or UCL School of Pharmacy ethics approval. The study was approved and supported by the relevant trust's Medication Safety Review Group which was responsible for providing strategic direction to the trust on medication safety. A summary of the proposal was sent to all the Heads of Nursing approximately three weeks prior to the start of the study and the relevant ward managers contacted prior to the start of data collection to obtain their consent. Nursing staff were informed of the objectives of the study, and that participation was voluntary, prior to starting data collection. A participant information leaflet was also

available if further information was requested. All nurses were encouraged to complete the drug round as per their usual routine and were informed that the observer would not talk or interrupt them during the drug round. Verbal consent was obtained from each nurse by the observer prior to shadowing them on the drug round.

5.4 Results

5.4.1 Characteristics of wards, participants and drug rounds observed

Forty-eight wards across all three sites met the inclusion criteria. Of these, the night staff on 11 wards (23%) administered doses for the morning round at approximately 6am rather than at 8am. This made observations more challenging logistically due to the limited public transport available for observers at that time of day. However, the observers were able to get to the relevant wards for four 6am drug rounds; seven wards were excluded, and a total of 41 wards therefore included in this study. Characteristics of included wards, drug rounds and participants are summarised in table 5.1. Inter-observer reliability per drug round was fair to excellent: median kappa per drug round was 0.76 (range 0.43 to 1.00). No interventions were made by the observers.

Table 5.1 Characteristics of wards, drug rounds and participants observed

	Site A	Site B	Site C	All sites
Wards				
Number of wards at each site	26	24	29	79
Number of eligible wards	15	14	19	48
Number of wards observed	13	14	14	41
Median number of beds per ward (range)	23 (15 to 26)	22 (13 to 44)	18 (8 to 37)	21 (8 to 44)
Number of drug rounds				
Morning (approx. 6am)	1	0	3	4
Morning (approx. 8am)	12	16 [a]	11 [b]	39
Lunchtime (approx. 12pm)	13	16 [a]	15 [c]	44
Number of patients observed (regardless of whether or not a dose was administered)[d]				
Total observed per site	133	200	155	488
Median per drug round (range)	5 (2 to 8)	6 (2 to 17)	5 (3 to 14)	5 (2 to 17)
Missing and misplaced drug charts (of all patients on the drug round)				
Number of misplaced drug charts	10 (7.5%)	17 (8.5%)	7 (4.5%)	34 (7.0%)
Number of missing drug charts	0	0	0	0
Number of attempted dose administrations				
Total observed per site	396	586	382	1,364
Median per morning round (95% CI)	15 (10-35)	24 (11-43)	18 (11-27)	22 (15-27)
Median per lunchtime round (95% CI)	7 (3-10)	9 (4 -10)	6 (4-7)	7 (4-9)
Nurse participant on each observed drug round[d]				
Band 5 (staff nurse)	21 (81%)	21 (66%)	22 (76%)	64 (74%)
Band 6 (senior nurse)	4 (15%)	10 (31%)	6 (21%)	20 (23%)
Band 7 (sister)	1 (4%)	1 (3%)	1 (3%)	3 (3%)
Total	26 (100%)	32 (100%)	29 (100%)	87 (100%)
Nurse experience on each observed drug round[d]				
Median number of years (95% CI) Range	1.2 (0.5-2.0) 0.5-14	3.0 (1.0-5.0) 0.5-11	3.0 (1.5-5.0) 0.5-10	2.0 (1.5-3.0) 0.5-14
Nurse experience post qualification on each observed drug round[d]				
Median number of years (95% CI) Range	4 (1-11) 1-28	5 (4-12) 0.5-30	9 (3-10) 0.5-32	6 (4-9) 0.5-32

[a] Two wards were formally divided into two separate patient areas, each with their own team of nursing staff, and therefore two additional drug rounds were observed; one on each ward.

[b] One additional morning round was observed because the number of pedometer steps were not recorded and the observer had the opportunity to observe another nurse during the same shift, and one morning round was not observed because the time of morning rounds kept changing.

[c] One additional lunchtime round was observed because the observer had the opportunity to observe another nurse during the same shift.

[d] It was possible to observe the same nurse participants and same patients on separate drug rounds but this was rare; actual number of nurses and patients that were observed more than once unknown as nurse and patient identifiable data were not recorded.

CI, confidence interval.

All nurses observed at site A and B, and 22 (76%) nurses at site C reported no problems with being observed on the drug rounds. The remaining seven nurses reported feeling stressed, uncomfortable, awkward, a bit tense, intimidating, and generally did not like being observed. Drug rounds were reported as 'typical' by 77% of nurses observed at site A, 100% at site B, and 52% at site C. Seven reasons were reported for the 21 'atypical' drug rounds: (1) 10 drug rounds were considered easy or quiet because there were fewer doses, less patient problems and/or less interruptions than expected during the drug round, (2) nurses on three drug rounds administered medications to additional patients to the ones he/she was looking after, (3) two morning rounds were carried out by the night staff who reported that they see drug administration as the day staff's role, (4) two rounds were observed on one newly opened ward, (5) two nurses reported the drug round as 'atypical' due to the presence of a student nurse on the round, (6) one nurse reported higher than expected number of drugs were not in the bedside medication locker, (7) one drug round was completed by a bank nurse who was not sure what was 'typical' for the specified ward.

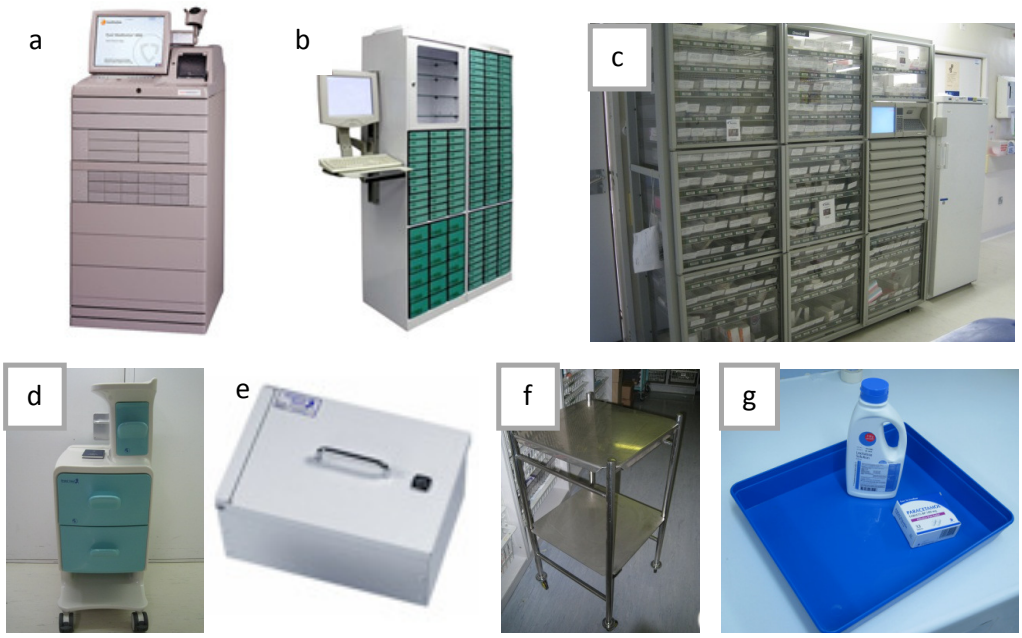
5.4.2 Medication storage locations available

The main differences in medication storage systems available between wards were: (1) whether wards had their own stock cupboards or shared with an adjacent ward, (2) whether or not an automated storage cabinet was used for storing CDs, (3) whether or not bedside medication lockers were available, (4) the number of conventional drug trolleys available (if any), and (5) whether or not other storage facilities were used to store a selection of ward-stock medications.

As might be expected, all wards had a fridge and CD cupboard. Thirty-nine wards (95%) had medication stock cupboards; the remaining two wards shared stock cupboards with an adjacent ward. Five wards (all at site A) also had an automated storage cabinet for storing

CDs (Pyxis® MedStation®, figure 5.1a) and two wards (one at site B, one at site C) additional housed an automated storage cabinet for out-of-hours use (site B: ServeRx®, figure 5.1b and site C: Omnicell®, figure 5.1c).

Figure 5.1a to f in order: Pyxis® MedStation®, ServeRx® medicines cabinet, Omnicell® medicines cabinet, key-less radio-frequency identification controlled bedside medication locker, transportable metal locker, temporary trolley, plastic tray.



The vast majority of wards also had bedside medication lockers for storing patient specific medications (39; 95%), of these one ward was trialling a set of key-less radio-frequency identification controlled bedside medication lockers (figure 5.1d). There was variation among sites in the percentage of wards that had conventional drug trolleys: five (38%) wards at site A, four (27%) at site B and ten (71%) at site C had at least one conventional drug trolley (median one drug trolley per relevant ward, range one to four). Separately, five wards at site C also stored a selection of ward-stock medications in transportable containers: three used metal lockers (figure 5.1e) and two used large plastic boxes. All wards additionally had other

types of trolleys, for example, dressing trolley (figure 5.1f), which some nurses used as a temporary drug trolley by placing medication from ward-stock directly onto it or one of the transportable containers. This was observed on two (15%) wards in site A, two (14%) in site B and four (29%) in site C. Additionally, one nurse at site A placed a selection of ward-stock medications into a plastic tray (figure 5.1g) for use on the drug round.

5.4.3 Success rate of medication retrieval

A total of 1,348 (98.8%) of 1,364 attempted doses were successfully retrieved and administered across all three sites. Of these, 19 were administered intravenously. The remaining 16 (1.2%) doses were omitted as they could not be found on the ward. Overall, 1,203 doses (88.2%) were retrieved from the first location searched: this meant approximately one in nine attempted doses was searched for in more than one location. Table 5.2 shows a breakdown of the number of locations searched per dose at each site (overall chi-square for all sites 11.4, p-value 0.003). Post-hoc analysis revealed significantly more doses were retrieved from the first location at site A than B.

Table 5.2 Number of attempted dose administration that were searched in one or more locations (% of attempted doses at each site).

	Site A	Site B	Site C	Total
One location	366 (92.4%)	500 (85.3%)	337 (88.2%)	1203 (88.2%)
Two locations	28 (7.1%)	85 (14.5%)	30 (7.9%)	143 (10.5%)
Three or more locations	2 (0.5%)	1 (0.2%)	15 (3.9%)	18 (1.3%)
Total	396 (100%)	586 (100%)	382 (100%)	1,364 (100%)

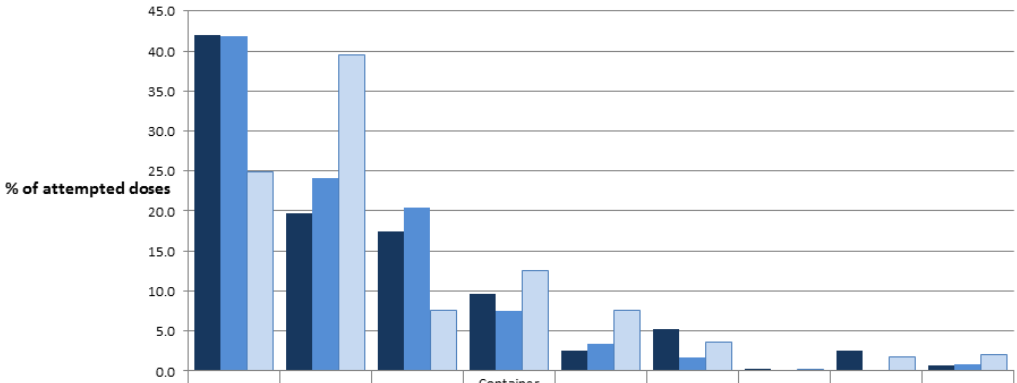
All 16 dose omissions due to drug being unavailable (1.2% of attempted dose administrations) occurred during the morning round: three on site A (three patients on two different drug rounds), five on site B (one patient) and eight on site C (seven patients on four

drug rounds). Three omitted doses (19%) were on the relevant ward's stock list and the remainder were not. The omitted drugs prescribed were: aciclovir, Adcal D3® (calcium carbonate and colecalciferol), Adcal D3® soluble, alfacalcidol, chloramphenicol eye drops, clopidogrel, ferrous fumarate, Femoston® (estradiol and dydrogesterone), isosorbide mononitrate, losartan, paroxetine, penicillin V, sevelamer, spironolactone, and two doses of bisoprolol. Five other doses were also omitted during the observations but the nurse did not attempt to administer these as he/she knew in advance that the dose was not available. The overall dose omission rate due to the drug being unavailable was therefore 1.5% of OEs.

5.4.4 Types of medication storage locations where doses were retrieved from

Of 1,364 attempted dose administrations across all three sites, doses were most commonly retrieved from the patient's bedside medication locker (37%), followed by the conventional drug trolley (27%), and stock cupboard (16%). Figure 5.2 shows the percentage of attempted dose administrations which were retrieved from different storage locations on each site.

Figure 5.2 Comparison of locations where attempted doses were retrieved from between sites.



	Bedside medication locker	Conventional drug trolley	Stock cupboard	Container +/- temporary trolley	Bedside area (not in locker)	Fridge	Controlled drugs cupboard	Other	Not found
Site A (% of 396 doses)	41.9	19.7	17.4	9.6	2.5	5.3	0.3	2.5	0.8
Site B (% of 586 doses)	41.8	24.1	20.5	7.5	3.4	1.7	0.0	0.2	0.9
Site C (% of 382 doses)	24.9	39.5	7.6	12.6	7.6	3.7	0.3	1.8	2.1
p-value (χ2)	0.000	0.000	0.000	0.032	0.001	0.007		0.004	
sites which differ (post-hoc)	C and A C and B	C and A C and B	C and A C and B	B and C	C and A C and B	A and B	insufficient data	A and B	insufficient data

'Other' locations where medications were retrieved from were as follows:

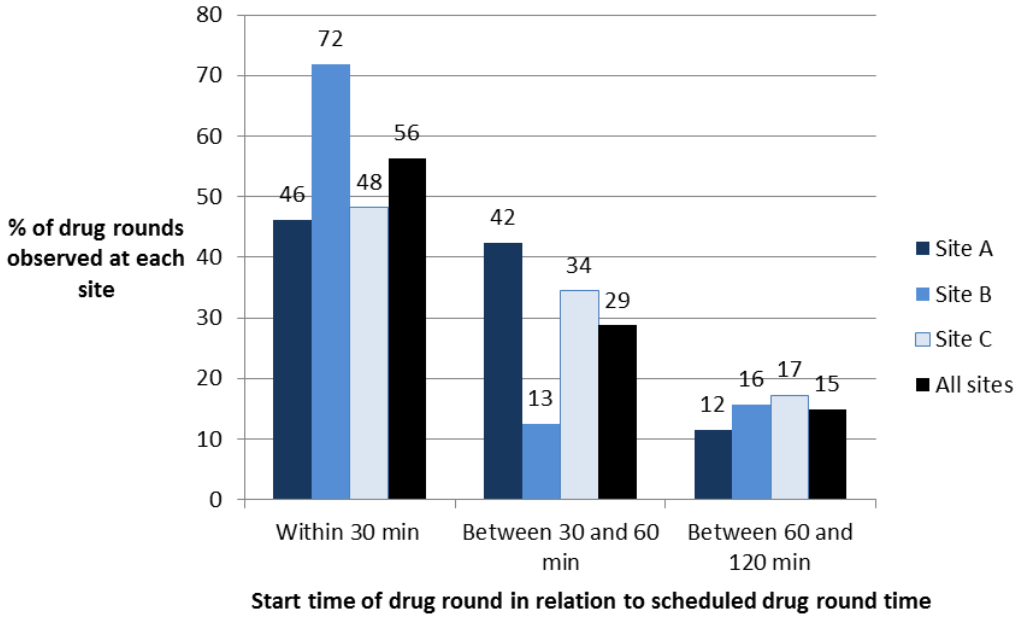
- the patient's bag (six doses for the same patient, site A),
- another ward (five doses for four patients, site C),
- another patient's bedside medication locker (four doses for four patients, two at site A and two at site C),
- pocket of the nurse doing the drug round observed (two doses for two patients, site A),
- pocket of another nurse i.e. not the one doing the drug round observed (one dose, site B)

Of the 19 wards that had at least one conventional drug trolley, 17 also had bedside medication lockers and two did not. A sub-analysis of storage locations accessed on wards with both a drug trolley and bedside medication lockers revealed that nurses were more likely to look in the drug trolley first than in the patient's bedside medication locker for a dose (75.4% and 11.9%, respectively, of 488 attempted dose administrations from 33 drug rounds). Three hundred and eighty two (78%) of the 488 attempted dose administrations were for drugs that were on the relevant ward's stock list. Of the 106 doses that were not on the ward's stock list, 26 (25%) were first searched for and retrieved from the drug trolley.

5.4.5 Duration and timeliness of medication administration

Across the three sites, median morning round duration was 43 minutes and median lunchtime round duration was 21 minutes (95% CI for the difference 8-37 minutes). Figure 5.3 shows the timeliness of drug round start times observed between the three hospital sites. Overall, 12-17% (equivalent to approximately one in every six to eight) of drug rounds were started more than 60 minutes from the scheduled drug round start time.

Figure 5.3 Comparison of timeliness of drug rounds between hospital sites.



5.4.6 Pedometer steps

Across the three hospital sites, the median number of pedometer steps taken during morning rounds was 564 (95% CI 327-759) and lunchtime rounds was 293 (95% CI 169-341). Overall, nurses took fewer steps for each attempted dose administration during morning rounds than lunchtime rounds: the median number of steps for each attempted dose administration was 23 (95% CI 16-30) and 44 (95% CI 34-53), respectively.

5.4.7 Exploratory analysis of the effects of different medication storage systems

Based on analysis of medication storage locations used across all three sites, three subtypes of the medication distribution system on drug rounds were identified:

- System 1: a system that involved using at least one conventional drug trolley on the drug round regardless of whether or not patients' bedside medication lockers were used (used on 19 wards (46%); 41 drug rounds)

- System 2: a system that involved using an 'alternative' drug trolley solution i.e. a container with or without a temporary trolley regardless of whether or not patients' bedside medication lockers were used (used on nine wards (22%); 21 drug rounds)
- System 3: a system without a conventional drug trolley or 'alternative' drug trolley solution i.e. a system that relied on the use of bedside medication lockers (used on 13 wards (32%); 25 drug rounds)

Characteristics of wards, drug rounds, and participants observed according to the type of medication storage system used are summarised in table 5.3. There were no significant differences between sites in the reported characteristics, however the relatively wide 95% CI suggests there was insufficient sample to detect differences in median values between systems.

Table 5.3 Comparison of characteristics of wards, drug rounds and participants observed between three different medication distribution systems: system 1, wards with at least one conventional drug trolley; system 2, wards with an 'alternative' drug trolley solution; system 3, wards with no trolleys.

	System 1	System 2	System 3	Difference between systems
Number of wards observed	19	9	13	
Number of drug rounds observed				
Morning rounds	20	11	12	p = 0.101 (chi-square test for all systems)
Lunchtime rounds	21	10	13	
Total	41	21	25	
Number of patients [a]				
Total observed	246	121	121	
Median per drug round	5	5	5	p = 1.000 (Kruskal-Wallis)
(range)	(2 to 17)	(3 to 9)	(2 to 8)	
Missing and misplaced drug charts				
Number of misplaced drug charts (% of patients)	17 (6.9%)	4 (3.3%)	13 (10.7%)	p = 0.076 (chi-square test for all systems)
Number of missing drug charts (% of patients)	0	0	0	
Number of attempted dose administrations				
Total observed	533	357	474	
Median per morning round (95%CI)	17 (11 to 23)	26 (11 to 40)	29 (10 to 53)	No significant difference (overlapping 95% CI)
Median per lunchtime round (95% CI)	5 (3 to 10)	7 (4 to 10)	9 (4 to 10)	
Nurse participants [a]				
Junior: Band 5 (staff nurse) Senior: Band 6 and Band 7	32 (78%) 8 (20%), 1 (2%)	15 (71%) 5 (25%), 1 (5%)	17 (68%) 7 (28%), 1 (4%)	p = 0.467 (chi-square test for all systems)
Total	41 (100%)	21 (100%)	25 (100%)	
Nurse experience on the ward observed [a]				
Median number of years (95% CI)	2 (1 to 3)	4 (2 to 8)	2 (1 to 4)	No significant difference (overlapping 95% CI)
Nurse experience post qualification [a]				
Median number of years (95% CI)	7 (3 to 12)	10 (4 to 17)	4 (2 to 6)	No significant difference

[a] *It was possible to observe the same nurse participants and same patients on separate drug rounds but this was rare; actual number of nurses and patients that were observed more than once unknown as nurse and patient identifiable data were not collected.*
CI, confidence interval.

The success rate of medication retrieval was similar across the three systems, table 5.4. However, the number of doses that were searched for in multiple locations was significantly different between sites (chi-square test for all systems 12.63, p 0.002), post-hoc analysis revealed that significantly more doses were searched for in multiple locations in system 3 (75; 15.8%) than systems 1 (57; 10.7%) or 2(29; 8.1%).

Table 5.4. Comparison of outcome measures between three different medication distribution systems: system 1, wards with at least one conventional drug trolley; system 2, wards with an 'alternative' drug trolley solution; system 3, wards with no trolleys.

	System 1	System 2	System 3
Number of attempted dose administrations	533	357	474
Median per drug round (range)	18 (2 to 46)	26 (2 to 44)	18 (1 to 61)
Successful dose retrieval (%, rate)	527 (98.9%)	353 (98.9%)	468 (98.7%)
Number (%) of doses searched for in more than one location	57 (10.7%)	29 (8.1%)	75 (15.8%)
Median duration per dose attempted per drug round, minutes (95% CI)			
Morning round	2.2 (1.4 to 3.0)	1.9 (1.3 to 2.5)	1.6 (1.0 to 2.2)
Lunchtime round	4.0 (3.0 to 5.0)	3.0 (1.6 to 4.3)	3.1 (1.6 to 4.6)
Median number of steps per dose per drug round (95% CI)*			
Morning round	27 (15 to 39)	22 (11 to 34)	17 (6 to 29)
Lunchtime round	53 (25 to 81)	32 (18 to 45)	37 (18 to 56)

Shaded boxes indicate order of magnitude of results: ■largest result, ■ 2nd largest result, and ■ smallest result.
** four drug rounds were excluded as the pedometer did not record the number of steps. CI, confidence interval.*

Overall, system 1 was associated with the longest time taken per attempted dose administration and greatest number of steps per attempted dose administrations during both morning and lunchtime rounds; however, overlapping 95% CI indicate that there these were not statistically significant, table 5.4.

5.5 Discussion

5.5.1 Main findings

Overall, this study identified a number of differences in the types of medication storage facilities available and the frequency with which they were used among 41 general medical and surgical wards of one NHS trust. Three main subtypes of the medication distribution system used on non-IV drug rounds were identified which differed in terms of whether or not

a conventional drug trolley or an 'alternative' drug trolley solution was used in addition to patients' bedside medication lockers. Exploratory comparisons between these three systems revealed no significant difference in the rate of successful dose retrieval, timeliness of medication administration, or physical steps taken by nursing staff during non-IV drug rounds.

Overall omissions due to drug being unavailable occurred in 1.2% of attempted dose administrations or 1.5% of OEs, which is comparable to previous observation studies in UK hospitals (1.2-1.7% of OEs for non-IV doses)(chapter three; M^{c}Leod et al., 2013). However, this was despite the nurse searching in multiple locations for approximately one in every nine doses. In general, doses were most commonly retrieved from the patient's bedside medication locker, except on wards which had at least one conventional drug trolley. On these wards, the drug trolley was the most common location used to retrieve medications. Across all wards, 15% of drug rounds (approximately one in six) were started 60-120 minutes from the relevant scheduled round time. Nurses took longer, and more steps per attempted dose administration, during lunchtime rounds than morning rounds, with an overall median of 2.5 minutes per attempted dose administration and a median 31 steps per attempted dose administration (95% CI 26-37).

5.5.2 Use of medication storage systems during non-IV drug rounds

As might be expected, patient bedside medication lockers were widely used across the study wards. However, intra-hospital variation was identified in: whether or not conventional drug trolleys were used, the number of conventional drug trolleys used, and the use of 'alternative' drug trolley solutions. These types of variation have not previously been described in published studies but the commercial availability of some of the 'alternative' drug solutions suggests their use may be well-established.

While the successful dose retrieval rate was comparable between the three systems, exploration of successful first location retrieval revealed a difference in use between the three systems. The use of a conventional drug trolley or an 'alternative' drug trolley solution was associated with more successful first location retrieval than when neither type of drug trolleys were used. This may seem counter-intuitive initially as the use of any type of drug trolley introduces an additional storage location for the nurse to search for medication. Three factors may explain this; first, the underlying assumption that an additional storage location affects the success of first location retrieval is that the nurse will always search for a dose in the bedside medication locker before any type of drug trolley. In practice, observations revealed nurses searched in the bedside medication locker first for 43% of all attempted dose administrations. Second, is the related assumption that the nurse has no prior knowledge or expectation of where the required dose is stored; therefore different storage locations would be searched in the same order for each dose. However, findings from the current study suggest otherwise; 18 doses were first searched for in 'other' storage locations including a patient's bag, another ward, another patient's bedside medication locker, and nurse's pocket. Furthermore, five doses were omitted and the nurse did not attempt to administer these during the drug rounds observed as he/she knew in advance that the dose was not available. Third is the assumption that nurses use the medication storage systems in the same way. In practice, a number of 'informal' differences between nurses on different wards and even on the same ward was observed. For example, nurses were observed decanting a selection of medicines from a conventional drug trolley to a temporary trolley for use on one ward. On another ward, one nurse used a plastic tray to transport a selection of commonly used ward-stock medications on the drug round while another nurse did not.

Other studies have also identified variations in nurse practice even on the same ward. One study investigating the accuracy of documentation of administration on drug charts observed

1,002 dose administrations noted that "some nurses kept all medicines in the drug trolley, whereas others preferred to put individually dispensed preparations, such as mouthwashes, glyceryl trinitrate tablets, topical preparations and inhalers by the patient's bedside (Dean et al., 1998). This sometimes resulted in the omission of medication if the nurse could not find the drugs where he/she expected to find them". In another study, researchers found nurses frequently deviated from trust policy in what was termed "correct violation" when they used PODs on wards without patient bedside medication lockers, in order to administer a dose (Dean & Barber, 2000).

More importantly, these observations highlight the adaptability of nursing staff to their work environment and the potential unintended consequences of some ward-based medication systems on drug round workflow. A few studies have begun to explore these unintended sociotechnical interactions in relation to medication administration. However these have mainly focused on workarounds (informal practices in response to a temporary problem), rather than informal practices to 'pre-empt' potential recurrent problems or have been specific to technology that are less common in UK hospitals such as barcode administration (Patterson et al., 2002; Carayon et al., 2007; Koppel et al., 2008).

Based on observations during the study, some nurses were seen to pre-emptively minimise the problem of searching in multiple locations by going through the whole drug chart before retrieving the doses required. Another nurse took two drug charts to the stock cupboard and prepared most of the doses there before going to retrieve the remaining doses from the patients' bedside medication lockers. Using a human factors approach (Reason, 1990; Norman, 1988) together with the exploratory analysis findings, these observations suggest the success rate of retrieving a dose from the first location is more likely to be associated with nurses' prior knowledge of the locations in which they expect medications to be stored rather than just the availability of the drug trolleys. The use of a drug trolley probably

facilitates the development of this knowledge by providing a visual reminder of which medications are ward-stock.

5.5.3 Duration and pedometer steps taken for each dose

Overall, the duration and timeliness of drug rounds were comparable to previous studies in the UK; observational studies found 13-50% for non-IV doses were administered more than 60 minutes from the time for which the dose was due (chapter three). While the sample in this exploratory analysis was too small to detect timing differences in seconds or pedometer steps between systems, the data for comparing timing and steps between morning and lunchtime rounds suggest lunchtime rounds were consistently less 'efficient' than morning rounds. Possible reasons for the lunchtime round being less efficient include the following: fewer doses were required at lunchtime but nurses still have to visit each patient, more interruptions and/or distractions due to the presence of more ward staff, and a higher general level of activity on the ward.

5.5.4 Implications for practice

Findings from this study suggest that different nurses varied in how they used the same types of medication systems; these may have had an influence on successful retrieval rates, duration, and number of steps per dose. Given the variation in nurse practices observed, it might be useful to consider identifying a set of standard 'best practice' locally on the ward to align the knowledge and expectations of nursing staff as to where medications should be stored. A multi-disciplinary health care professional approach would potentially be useful as there are a number of different stakeholders that access patients' medications in the hospital. The types of medication storage to use on a ward can then be considered based on whether or not it is suitable for supporting local best practice. As the 'standard' practice becomes routine on the ward, this approach may also allow nursing staff to quickly identify

problems associated with the medication storage system because informal practices are more likely to stand out.

Short-term, other suggestions for practice include: (1) review ward-stock levels of drugs as inappropriate over or under stocking may impede timely dose retrieval, and (2) for drugs that are used in large quantities for multiple patients, consider storing the drugs in a central location and take what is required on the drug round via an alternative drug trolley solution if a drug trolley is not used. Incorporating the findings from the national survey data (chapter four), a medium-term suggestion is to review the need for OSD on long-stay wards (more than two weeks). This is because OSD was primarily introduced to reduce re-dispensing for discharge, and therefore mainly useful for wards with less than two-week inpatient stays and/or where patients tend to self-administer. Long-term, the potential implications of implementing EPMA systems on drug rounds should also be considered. These systems may allow opportunities such as other technological devices to be developed and/or implemented to facilitate medication ordering and identifying medication availability in different locations.

5.5.5 Strengths and limitations of this study

Strengths of the current study include: (1) use of direct observation, (2) observations on a large number of wards with different medication systems and ward layouts, (3) dose administrations to patients for a range of general medical and surgical specialties were observed, and (4) inter-observer reliability was assessed and data collection found to be comparable between observers and MM. The main study limitation was the small number of drug rounds observed on each ward for the exploratory medication system comparison analysis. A number of potential confounding factors were identified: differences between individual nurses, the level of nurse experience on the ward, layout of the ward with respect to distance between stock cupboards and patients, number of patients on the drug round,

number of doses due and attempted on the drug round, number of IV doses given during the drug round, time of day, proportion of medications which were ward stock, the number of misplaced drug charts, the number and duration of interruptions, and the number of distractions. Although these confounding factors could not all be taken into account during the analysis, the majority were documented and reported. A larger study with multiple logistic regression analysis would be required to explore the impact of a wider range of factors. Separately, 11 wards (23% of eligible wards) administered medications at approximately 6am rather than 8am. This was unexpected, as it was the research team's understanding, from the Nurse Directorate, no drug rounds were scheduled for 6am on any inpatient wards. This suggests a change in work practice that may have been made at the ward level but not communicated outside the ward. The early morning drug rounds was a limitation in the present study as this led to the exclusion of seven wards. Finally seven nurses reported a negative experience with being observed which may have influenced their behaviour on the associated drug rounds. There was no indication during joint observations (MM and student) that any of the students' behaviour might be received negatively. However, on further investigation, it was identified that one of the student observers would actively encourage nurses to express their opinion on being observed more so than the other two students at the end of the drug rounds. This may have contributed to nurses being more open about their experience.

5.6 Conclusion

Intra-hospital variation in the number and types of ward-based medication storage facilities available exists. Current practices of medication storage and retrieval in one NHS trust differed between different wards and even between nurses on the same ward. A number of wards had developed different 'alternative' drug trolley solutions that have not previously been described in the literature. Exploratory analysis comparing the effects of three different

medication distribution systems used on non-IV drug rounds revealed no significant difference in the rate of successful dose retrieval, timeliness of medication administration, or physical steps taken by nursing staff, however a study with a larger sample is required to confirm this. Further research is required to better understand the sociotechnical interactions between nursing staff and the medication systems used for drug administration. Thus, an ethnographic study of medication administration processes and systems used by nursing staff was conducted and is described in the next chapter.

Chapter 6. An ethnographic study of medication administration processes and systems (MAPS study): effects on medication safety, workflow, interruptions, and distractions

6.1 Introduction

Following the national survey of medication systems in English NHS hospitals (chapter four), and the medication storage system study in one NHS trust (chapter five), a number of potential system variations that may contribute to safer medication administration were identified. This chapter describes a study to explore in more depth the interactions between systems factors, nurses working within different medication systems, and safe medication administration.

6.2 Background

Errors at the medication administration stage are common; occurring in 3.0-8.0% for non-IV doses and 9.3-53.8% for IV doses administered to NHS hospital inpatients (chapter three; M^{c}Leod et al., 2013). Although a number of studies have measured the incidence of MAEs

and identified their potential causes, few have examined this area from the other perspective: how do staff work within the NHS hospital system to administer drugs safely and successfully?

Poorly designed systems and overly complicated processes can increase the risk of an error occurring, while carefully designed systems and more streamlined or simpler processes may reduce this risk (Reason, 1990; Perrow, 1984). As Leape (1995) highlighted, "the objectives of system design for safety are twofold: (1) to make it difficult for individuals to err, and (2) to "absorb" errors that do occur i.e. permit their detection and correction before harm occurs". In the past, research has focused on investigating systems effects on patient safety (Leape et al., 1995; Grout, 2007). However, few have applied the human factors approach to investigating the medication administration process in detail.

Several reviews have reported on the individual and systems factors that contribute to MAEs (chapter one). In the most recent review by Brady et al (2009), the researcher emphasised the importance of six main contributory factors in relation to medication administration: different types of drug distribution systems, quality of prescriptions, deviation from procedures, medicines reconciliation, excessive workloads, and nurses' knowledge of medications. However, insufficient methods were reported and exclusion of known relevant studies in this area (Franklin et al., 2007; Dean & Barber, 2000; Taxis et al., 1999; Dean et al., 1995) from Brady's review limited interpretability of the reviewers' findings regarding comprehensiveness and importance of the factors identified.

In relation to specific studies, systems-related factors such as the work environment, equipment availability, processes of work, workflow, and interruptions have been found to contribute to an individual's risk of making an error (Popescu et al., 2011; Westbrook et al., 2010). While it is important such system-wide causes of MAEs are identified, this only

provides us with information about what systems and processes do not work so well and not what does work well. For example, studies of reworks and workarounds associated with medication administration suggest that these deviant processes are relatively common and can create 'more holes in the system', bypassing essential safety defence barriers, and thereby increasing the risk of an incident occurring (Halbesleben et al., 2008; Koppel et al., 2008). However, in some cases, such deviant processes may be considered as pre-emptive actions to increase efficiency and/or minimise potential for error (chapter 5) and may act as an indicator of underlying latent conditions for potential future incidents. Thus, it is important to not only identify potential contributory factors to MAEs but also how individuals manage them within the limits and resources available to them. The latter are additionally relevant given the ever increasing financial and resource constraints imposed on the NHS.

Following the responses obtained from the recent national survey of medication systems in English NHS hospitals (chapter four), a number of potential system variations that may contribute to safer medication administration were identified. In addition, observations during the earlier preliminary observational study (chapter two) and medication storage study (chapter five) identified a number of variations in how individual nurses carried out medication administration tasks. To explore these further, the current study was developed to better understand how nurses' medication administration practices may be affected, both intentionally and unintentionally, by different system factors.

6.3 Aim and objectives

The aim of this study was to describe systems factors that facilitate and/or hinder successful drug administration. There were four objectives:

1) To describe individual nurse practices and workarounds that potentially influenced MAEs in different medication systems;
2) To identify systems factors that facilitate and/or hinder medication administration workflow;
3) To identify individual and systems factors that potentially affect the frequency and nature of interruptions and distractions that occur during medication administration;
4) To make recommendations for potentially improving the system and process of medication administration to reduce MAEs, streamline workflow, and reduce unnecessary interruptions and distractions.

6.4 Methodology

This section describes five main methodological considerations in designing the study: (1) the rationale for using an ethnographic approach, (2) recording observations, (3) data analysis – theoretical approach and conceptual framework, (4) assessing authenticity, plausibility, and criticality, and (5) minimising researcher bias.

6.4.1 The rationale for using an ethnographic approach

Three main qualitative research traditions were considered for use in this study, table 6.1. The central aims of each were considered and the ethnographic approach was considered to be the most appropriate as ethnography seeks to understand behaviours in context and is not bound by the limitations of self-reporting.

Briefly, ethnography has been described as “a way of looking” (observing) and “a way of seeing” (experiencing) human social behaviour (the culture) (Wolcott, 2008). It has its origins in anthropology and is about understanding the lived experience of people through immersion in their community and of observations in the real-world rather than under

experimental conditions (Greenhalgh & Swinglehurst, 2011). Savage (2000) suggested a number of ways in which ethnography may be applied in health care, one of which was that ethnography can help to identify how an organisations' formal structure, such as the rules, are influenced by an informal system that may be created by individuals or groups of individuals within the organisation.

Table 6.1 Types of qualitative research approaches and considerations for their use in the medication administration processes and systems (MAPS) study (Ritchie & Lewis, 2003)

Research tradition	Aims	Appropriateness for the MAPS study
Phenomenology/ ethnomethodology	To understand the 'constructs' people use in everyday life to make sense of their world. Phenomenology seeks to uncover meanings contained within conversation or text while ethnomethodology is focused on methods and practices used by people to make sense of their world.	Less appropriate – the overarching aim of the MAPS study was to explore how people *interact* with the world around them rather than how they *interpret* the world around them (although it was recognised that the two are linked).
Symbolic interactionism (leading to Grounded theory)	To explain how people behave as a result of the 'symbolic' meanings that people attach to action and things. Grounded theory takes the explanation further by studying how these 'symbols' relate to actions and things in certain situations and generating theory grounded in the data.	Less appropriate – the MAPS study was focused on people's behaviour as influenced by the *practicalities of the systems* rather than the *meanings* people attach to the systems. Furthermore, the MAPS study was exploratory and not aimed at generating theory.
Ethnography	To understand the cultural knowledge, behaviour and artefacts of a group of people through immersion in their community.	Most appropriate – see explanation in main text.

The value of the ethnographic approach for the current study was that it allowed subtle behaviours (related to the medication administration process) that an individual (nurse) may

not be aware of, as well as explicit interactions and features to be identified within the context of the medication system used on the study wards. This included an insight into how resources were being used, whether or not they were used as intended, what work processes and/or workarounds existed under certain situations, and their potential effects on medication safety.

6.4.2 Recording observations

Direct observation is the principal method of ethnographic studies. Broadly, qualitative observational data may be recorded as text in the form of field notes by the researcher, as audio in the form of naturally occurring talk that has been taped, or as visual images in the form of video and photographs (Green & Thorogood, 2009; Silverman, 2011). The decision as to how observations are recorded is largely dependent on the objectives of the study and the practicalities of the setting. However, it is perhaps more useful to consider that:

> *"The critical task in qualitative research is not to accumulate all the data you can, but to 'can' (i.e. get rid of) much of the data you accumulate. That requires constant winnowing, including decisions about data not worth entering in the first place. The idea is to discover essences and then to reveal those essences with sufficient context, yet not become mired by trying to include everything that might possibly be described."*
>
> Wolcott *(1990; p35)*

Bearing the above in mind, a mixture of field notes and photographs (rather than audio and video recording) was used to record the organisational practices of medication administration by nursing staff. This approach enabled the researcher (MM) to follow and observe nurses relatively more discreetly as they worked and travelled to different parts of the ward and minimised researcher obtrusion on staff and patients. Field notes comprised

both observations of and narratives from nursing staff as they carried out their routine tasks; this included 'mapping' the path of travel by nurses during the drug round. Field notes collected in this way were relatively flexible and allowed some of the nurses' rationale for their actions to be explored. The level of abstraction was not determined *a priori* in order to explore interactions at different levels between 'humans' and 'systems'; field notes documented include the smallest level of abstraction which Lofland and Lofland (1995) described as 'practices' (an activity that the participants regard as unremarkable normal feature of on-going life) to the highest level 'lifestyles or subcultures' (the global adjustments to life by large numbers of similarly situated persons). Photographs were taken of the work environment and medication systems to facilitate recall and data analysis.

Typically, ethnographic studies comprise mixed methods to combine qualitative and quantitative data. Additional quantitative data were also recorded during observations to facilitate interpretation of sociotechnical interactions in different settings, and to enable some aspects of the current study to be compared with relevant studies in the literature.

6.4.3 Data analysis – theoretical approach and conceptual framework

Despite the use of some quantitative data, ethnography is a qualitative research tradition. All types of data are analysed qualitatively and concurrently (rather than focusing on field notes separately to photographs or separately to the quantitative data) to identify concepts and themes. This contributes to the understanding or explanation of the phenomena under study (Miles & Huberman, 1994). Miles and Huberman (1994) defined three concurrent processes involved in analysing data:

- ***Data reduction*** is the process of selecting, filtering, abstracting, reviewing, and transforming the data to allow inferences to be made that contribute to the final conclusion
- ***Data display*** is the process of organising and compressing information to facilitate further data reduction and identification of themes that contribute to the final conclusions
- ***Conclusion drawing/verification*** is the process of identifying patterns, deriving explanations, and testing the conclusions drawn for their 'plausibility, sturdiness and confirmability' (also known as validity)

The processes described by Miles and Huberman (1994) formed the general approach used in the present study. However, there are a number of specific methods that influence how the processes are carried out; table 6.2 lists five qualitative data analysis methods with a summary of the considerations for their use in this study. Overall, the framework analysis approach was chosen as it allowed themes that were identified *a priori* to be used as an initial framework to guide data analysis; this was particularly useful for the current study which aimed to build on existing sociotechnical theory rather than generating new theories.

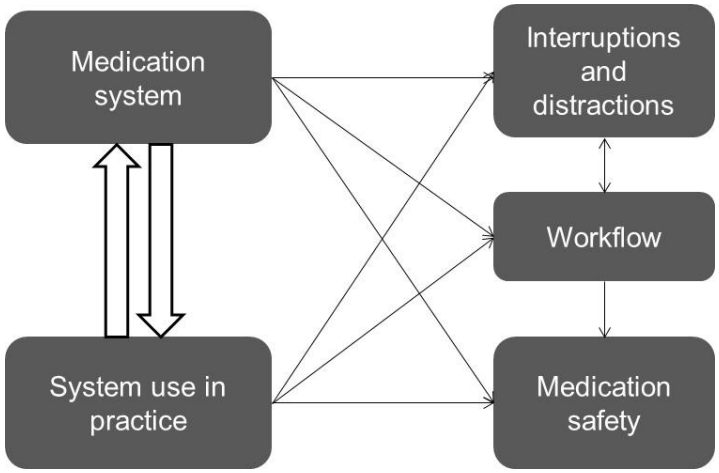
Table 6.2 Types of qualitative data analysis and considerations for their use in the medication administration processes and systems (MAPS) study (Ritchie & Lewis, 2003; Corbin & Strauss, 1990; Silverman, 2011)**.**

Analytic method	Description	Appropriateness for the MAPS study
Content analysis	Content analysis is an approach used to focus on the way themes are presented and involves identifying the frequency of their occurrence before linking the findings to external variables that may have contributed to their presence.	Less appropriate – the MAPS study was more about identifying and understanding sociotechnical interactions
Discourse analysis	Discourse analysis is used to understand the way knowledge is produced through language, including examination of linguistic styles and words used in order to identify implicit theories and how people make sense of the world.	Less appropriate – the MAPS study was more about identifying and understanding sociotechnical interactions
Interpretative phenomenological analysis	Interpretative phenomenological analysis is an approach used to understand an individual's perception of a given phenomenon under certain situations and how the individual's experiences contribute to their perceptions.	Potentially appropriate, however the MAPS study was more about identifying and understanding both the systems and human aspects of sociotechnical interactions rather than being more focused on the individual's perceptions.
Grounded theory	Grounded theory as a method of qualitative data analysis is a systematic approach for generating theory from data. Data analysis is driven by an iterative process of data collection and constant comparisons to test evolving theories until no new information emerge. As such, grounded theory is associated with sampling until data saturation.	Less appropriate –the MAPS study was exploratory rather than to generate theory.
Framework analysis	Framework analysis is a matrix-based method that allows for themes to be identified within and between cases. It also retains the context within which the data are analysed and allows for *a priori* themes to evolve during data analysis.	Most appropriate – see explanation in text

Framework analysis was developed at the National Centre for Social Research by Ritchie and Spencer during the 1980s (Ritchie & Lewis, 2003). It is a matrix-based analytic method for ordering and synthesizing data. Initially, the method involves familiarisation of the data to

identify key ideas, and recurrent themes. Next, a thematic 'framework' is produced, based on emerging themes from the familiarisation process or built on to an *a priori* thematic framework. Both approaches are considered appropriate provided the development of the final thematic framework is led by the emerging themes. In the current study, a thematic framework was identified *a priori* (figure 6.1) in order to facilitate data collection of specific aspects of sociotechnical interactions outlined in the objectives. The next stage of framework analysis is to develop a preliminary coding scheme from the thematic framework. An alternating process of observation and data analysis is required to develop the coding scheme; this was done in the current study by building on the experience gained from previous observations during the data collection period. This also allowed MM to observe the nurses in a manner which was flexible to their routines and identify specific areas for targeted observation at the next session. Once the coding scheme is established, the codes are applied to the whole dataset (indexing) and the data rearranged according to the thematic content (charting). Next, relationships between the codes are examined to identify and explore underlying associations between nursing staff practices and the medication systems used.

Figure 6.1 Initial thematic framework for studying systems factors on workflow, interruptions, and distractions on the safety of the medication administration process.



6.4.4 Assessing authenticity, plausibility, and criticality

Unlike quantitative experimental studies, ethnographic studies are evaluated on three main interpretive criteria: authenticity, plausibility, and criticality (Greenhalgh & Swinglehurst, 2011). Greenhalgh and Swinglehurst (2011; p4) described authenticity as "immersion in the case through extended fieldwork", thus emphasising the importance of reporting evidence to demonstrate that this was the case. In the current study, potential researcher bias was identified as a key factor that could have influenced authenticity; this is discussed separately in the next subsection. Plausibility was described as "developing explanations of local phenomena which made sense to participants and drawing these together into a coherent overall narrative" (Greenhalgh & Swinglehurst, 2011); this is a highly subjective task which has no obvious right or wrong outcome, thus it is vital that criticality is also incorporated. Criticality is the systematic questioning of assumptions made in describing the explanations of the phenomena under study; this is a continuous process which helps to refine the explanations, and thus strengthen the findings. As with any qualitative study, it is important to recognise that there is always some doubt about the significance of particular 'phenomena'; consequently, the report must provide explanations to support and identify the limitations of the researchers' interpretation. In the current study, both plausibility and criticality considerations formed a key component of the data analysis by the researcher; additional support to assess and explore these was provided by a PhD supervisor (BDF). Data were analysed iteratively until both researchers agreed on the final themes.

6.4.5 Minimising researcher bias

Ethnographic qualitative data obtained via observation requires the researcher to 'see' beyond the mechanics of the human interactions that occur within a specific culture or environment. To do this, the researcher must immerse themselves in the culture through a process of repeated data collection and analysis as "it is the analysis that drives the data collection… [and therefore] the researcher is shaped by the data, just as the data are shaped

by the researcher" (Corbin & Strauss, 1998). The researcher needs to find a way to maintain a balance between objectivity and sensitivity in collecting and analysing the data. Objectivity is required to ensure events are interpreted in an accurate and impartial manner. Subjectivity is required to explore the subtleties of practices observed and to identify potential connections between emerging concepts (Corbin & Strauss, 1998). It is also important to be reflexive in the data due to potential influence of the observer on the individuals being observed.

Researcher's background

An approach used in this study toward achieving the balance between objectivity and subjectivity was to recognise the viewpoints and preconceptions that I may have brought to the data in both data collection and analysis. As a hospital pharmacist for over 10 years, and previous research experience observing nurses administering medications, I am familiar with the fundamental systems and processes of medication administration in hospitals. My experience was advantageous in some ways as it facilitated the data collection process; I was probably more able to filter out and record relevant observations than an observer who is not familiar with NHS hospital medication administration related systems and processes. However, I may also have applied some tacit knowledge and/or assumptions from the hospital in which I work to the study site being observed. In order to identify and rectify these potential preconceptions, I sought clarification from nursing staff about the typical work processes during convenient times of their choosing. I also encouraged nursing staff to tell me their thoughts on the medication systems they were using, how they felt about being observed, and if there was anything I could do to improve. Feedback from nursing staff was recorded as part of the field notes, which subsequently provided additional guidance to me to further improve my data collection approach at each study site, and to facilitate some data analysis.

6.5 Methods

6.5.1 Selecting study sites

This was a follow up study from the national survey of medication systems in English NHS hospitals that was conducted in July 2011 (chapter four). Purposive sampling was used as it is considered a necessary prerequisite in qualitative research in order to identify cases most likely to show the issues or processes under investigation (Ritchie & Lewis, 2003). The aim was to sample for maximum variation.

First, one hospital was pre-selected by the researcher and both PhD supervisors for the following practical reasons: (i) 'typical' medication administration related systems and processes were reported to be in use from the survey (for example, use of paper drug chart, patient bedside medication lockers, drug trolleys), (ii) these were confirmed by the researcher and one of the PhD supervisors as both had a working knowledge of the hospital medication systems, (iii) the researcher had a substantive NHS contract with the hospital which minimised potential delays due to administrative processes, and (iv) the study had approval from the chief pharmacist.

Other potential study sites were then identified using the following selection criteria to maximise variation in medication administration related systems and/or practices for observation in this study: (i) at least one of the hospital medication systems or practices reported by the respondent has not been reported by more than 9 other respondent hospitals, (ii) the hospital medication system or practice must relate to inpatient medication administration rather than discharge or other parts of the medication process, and (iii) the respondent must have given consent in the questionnaire to be contacted for a future study. An initial shortlist of 24 potential hospitals was identified by the researcher and through discussions with both PhD supervisors the shortlist was subsequently reduced to 13

hospitals. Eleven hospitals were excluded as the systems or practices identified were considered to be mainly focused on facilitating hospital discharge (5), were standard hospital practice (4), or were used to potentially reduce turnaround times for inpatient medication supply (2). . Relevant survey respondents were then contacted by the researcher and a brief telephone interview was conducted by MM to find out further information. Responses were reviewed by the researcher and both PhD supervisors to confirm whether or not the medication administration systems and/or practices described were distinctly different to those at the pre-selected hospital. Subsequently, nine hospitals were identified for inclusion; three were excluded as the researcher was unable to reach the respondent and one was excluded after information from the respondent revealed that reported systems were for facilitating patient discharge rather than for medication administration related activities. A stepwise approach was used to invite study sites to participate, starting with hospitals located within commutable distance by public transport; this allowed the researcher to better plan data collection. Respondents were telephoned and emailed up to three times over a four-week period to arrange for a brief interview and invite them to participate in the current study. However due to time limitations, only five of the nine hospitals were invited to participate in the current study; four respondents could not be reached or were unavailable. Of the five hospitals that could be reached, two respondents declined to participate in the study because organisational changes were taking place at the time and one respondent accepted in principle but was later excluded due to delays in administrative processes. The remaining two respondents agreed to participate in the study and together with the initial pre-selected hospital formed a total of three sites for inclusion in the current study. Details of each study site are summarised in table 6.4 in the results section.

6.5.2 Participant consent

Overall consent for participation was obtained from the chief pharmacist and other relevant staff at each study site; identification of a suitable ward was coordinated by the contact person (respondent from the national survey, chapter four) at each hospital. A summary of the study protocol, participant information leaflet and consent form was provided to the contact person to facilitate local review and approval process. An honorary NHS contract was set up at two sites; the researcher had a substantive NHS contract with the third. Following all relevant approvals, the researcher liaised with the site contact person and ward manager regarding data collection. A participant information leaflet (appendix 14) was provided to all nursing staff observed on the ward and written consent was obtained (appendix 15). The researcher went through the participant information leaflet with each nurse including the objectives of the study, participation was voluntary, and all data would be anonymised.

6.5.3 Data collection

A convenient sample of nursing staff were observed during a full range of drug round times over seven to ten consecutive days at each study site. Data were collected by one pharmacist researcher MM, who observed nursing staff as they went about their usual routines. Observations were divided into 'qualitative' and 'quantitative' drug rounds. For both sets of observations, the researcher observed nursing staff as they went about their usual routines before, during and after scheduled drug rounds. General characteristics of the drug rounds observed were documented for both sets of observations: time of scheduled drug round, duration of drug round, number of patients, and number of steps taken by nursing staff (using a pedometer, Yamax Digi-Walker SW-200).

During the first set of observations, which were qualitative in focus, detailed descriptions of the medication administration process and systems used were documented as field notes, photographs, 'spaghetti diagrams' (map of travel), and narratives. In the second set of observations, the following quantitative data were documented: details of the medicines administered, storage locations accessed, number and sources of interruptions and distractions. Data collection was not focused on detecting MAEs but the number of opportunities for error was documented during the quantitative set of observations to determine an MAE rate of any MAEs that were detected. Initial data collection forms were piloted and the following key changes were made: (1) a section for documenting the general ward activities at around the time of the drug round was added, (2) a section for documenting feedback from nursing staff was added, (3) a section to document the location of the nurse when an interruption or distraction was observed was added, and (4) a section was added to document the medication stage when an interruption or distraction was observed. Separate data collection forms were finalised for use for the two sets of observations (appendices 16 and 17).

6.5.4 Definitions

Definitions, inclusion, and exclusion criteria for the quantitative data are summarised in table 6.3. Sources of interruptions and distractions were based on categories developed by Pape (2003) and were adapted for use in the current study (appendix 18). These are termed 'externally-initiated interruptions' in the present study as the definition by Pape (2003) was based on the individual attending to an external stimulus. In addition, the externally-initiated sources of interruptions were separated into two main groups: 'individual' and 'technical' as described by (Biron et al., 2009). This separation was useful as it organised the relatively long list of sources into smaller more practical lists for use during data collection, and as the origins of each group are distinctly different, Biron's grouping allowed the sources to be analysed and interpreted accordingly. Additionally, a separate 'self-initiated interruptions'

category was included to explore the potential effects of the individuals themselves on their own workflow.

Table 6.3 Summary of definitions, inclusion and exclusion criteria used in the quantitative part of the study.

Definition	Inclusion criteria	Exclusion criteria
Externally-initiated interruptions A situation in which a nurse ceased the preparation, administration, and/or documentation task before it was complete in order to attend to an external stimulus (Pape, 2003; Flynn et al., 1999).	▪ See appendix 18	▪ Self-initiated interruptions (see below) ▪ Interruptions that occurred in between preparation and administration tasks, for example, attending to a telephone call after drug preparation was complete
Self-initiated interruptions A situation in which a nurse ceased the preparation or administration task before it was complete without an observable external stimulus (developed for the current study)	▪ Nurse initiating communications with persons, including the observer ▪ See also appendix 19	▪ Interruptions that occurred in between preparation and administration tasks, for example, attending to a telephone call after drug preparation was complete
Distractions A stimulus from a source external to the nurse that was not followed by cessation of activity but by the nurse continuing productive efforts while responding in a manner that was observable (Flynn et al., 1999).	▪ Nurse talks to someone while continuing with the task ▪ Glancing up towards external source of distraction	▪ Change in pace of task without other signs of distraction
Opportunity for error (OE) This is the sum of all doses prepared, given or prescribed but omitted (Allan & Barker, 1990; Franklin et al., 2007).	▪ Both the preparation and administration stages had to be observed in order for the dose to be an OE ▪ Leaving a dose at the patient's bedside for the patient to take themselves	▪ Doses prepared and administered by the patient and/or carer
Medication administration error (MAE) A deviation from the prescriber's medication order as written on the patient's chart or electronic medication administration record (Allan & Barker, 1990)	▪ All doses prepared and/or administered that were observed irrespective of route of administration ▪ All regular, 'stat', 'when required' doses ▪ Errors prevented by the observer, patient or persons other than the nurse themselves ▪ See also list of MAE subcategories in appendix 20	▪ Wrong time errors ▪ Omissions for therapeutic reasons ▪ Omission due to patient not on the ward ▪ Procedural-related violations such as not checking the patient's identity prior to administration ▪ Oxygen ▪ Nutritional supplements ▪ Thromboembolic deterrent stockings ▪ Leaving a dose at the patient's bedside for the patient to take themselves

6.5.5 Data analysis

All field notes were transcribed into Microsoft Word and quantitative data were transcribed into Microsoft Excel by the researcher in between drug rounds. Early transcribing of field notes after observation was essential to maximise recall, elaborate on field notes, identify potential further areas to help focus subsequent observations, and to facilitate concomitant data analysis during data collection. All site and participant identifiable data were entered into a separate Microsoft Excel document.

The primary focus of data analysis was to identify themes relating to systems-based interactions between nursing staff and the systems used to carry out medication administration. All data were analysed using the framework analysis approach (Ritchie & Lewis, 2003). Examples of data documented as field notes and photographs taken at each study site are provided in appendices 21-26. An initial thematic framework based on the study objectives was produced during early data collection and analysis (figure 6.1). The researcher re-read the field notes to become familiar with the data, separated the field notes into smaller code-able items, and then mapped these on to the thematic framework to test the comprehensiveness of the major themes and identify subthemes (appendix 27 shows an example of an expanded thematic framework created during data analysis). Descriptions of major themes and subthemes were amended repeatedly throughout the data collection and analysis process as more field notes were documented, transcribed, reviewed, and coded. BDF independently reviewed several iterations of the expanded thematic framework and coding scheme based on the field notes and verbal feedback from the researcher. Once the coding frame was confirmed, all the field notes were indexed. Indexed field note items were organised into a matrix in Microsoft Excel; each column represented a separate subtheme, each row for a separate drug round. This allowed data to be analysed within drug rounds (across multiple columns) and across different drug rounds (down multiple rows). Initial cross-cutting themes were generated by reviewing the expanded thematic framework

diagrams, data within the matrix, spaghetti diagrams, photographs, and medication administration related documents provided by participants at the study sites. Additionally, BDF also indexed two sets of field notes from each study site (approximately 10% of all field notes recorded) to assess plausibility and criticality of the thematic framework, in addition to contributing to further developing the thematic framework. The final thematic framework, coding scheme, major themes, subthemes, and cross-cutting themes were produced through further iterative processes by the researcher with support from BDF.

Quantitative data were additionally summarised descriptively. An MAE rate was calculated for non-IV doses and IV doses (M^{c}Leod et al., 2013) where the total number of MAEs was divided by the total number of OEs, multiplied by 100. The second method for calculating MAE rates described in chapter three was not used as measuring MAEs was not the primary objective of the present study (M^{c}Leod et al., 2013). An interruption rate per drug round hour was calculated (Biron et al., 2009; Relihan et al., 2010): the total number of interruptions per drug round was divided by the duration of the drug round in minutes, and then multiplied by 60. A separate distraction rate per drug round hour, and a combined interruption and distraction rate per drug round hour was also calculated.

6.5.6 Ethics approval

Ethics approval was granted by the UCL School of Pharmacy in January 2011. NHS ethics approval was not required as this study was considered to comprise service evaluation.

6.6 Results

6.6.1 Overview

Overall, a total of 85 hours and 43 different nurses on 56 drug rounds were observed across the three study sites. One nurse at site A initially declined to be observed, but later changed her mind during the end of the data collection period at the site concerned. The nurse explained that she was newly qualified and required supervision initially to give medications but was later able to give medications unsupervised. Characteristics of study sites and a summary of data collected at each site are summarised in table 6.4. During the quantitative observations, 458 doses were included as OEs (445 non-IV and 13 IV doses). The MAE rates were 2.7% of non-IV OEs (95% CI, 1.2 to 4.2) and 30.8% of IV OEs (95% CI, 26.3 to 35.2).

Table 6.4. Characteristics of study sites and summary of data collected.

Study sites	Staffing	Medication systems and administration processes	Observations
Site A 27-bed vascular and cardiology ward in an acute hospital of an acute NHS trust, London	▪ Ward: 24 RN ▪ Observed nurse to patient ratio: ○ Day shift – 1:8 ○ Night shift – 1:8 ▪ Nurse participants reported fewer staff than normal during the data collection period	▪ Paper drug chart ▪ 4 x drug trolleys ▪ RFID controlled electronic bedside medication cabinets ▪ Nurse administered drugs to patients they were looking after	▪26 March to 3 April 2012 ▪14 RN (inc. 2 bank/agency) ▪18 drug rounds (three at 6am and five each at 12pm, 6pm and 10pm) ▪Total 27 hours of observation, of which 15 hours 20 min were during drug rounds; the remainder were before and after drug rounds
Site B 28-bed adult elective surgical ward in an acute hospital of a foundation NHS trust, London	▪ Ward: 16 RN ▪ Observed nurse to patient ratio: ○ Day shift – 1:6 ○ Night shift – 1:6 ▪ Nurse participants reported fewer patients than normal during the data collection period	▪ Trust-wide EPMA system since 2008 ▪ EPMA access: two desktop computers, three tablet devices, and one COW ▪ 2 x drug trolleys ▪ RFID controlled electronic bedside medication cabinets ▪ Nurse administered drugs to patients they were looking after	▪ 20-31 August 2012 ▪ 13 RN (inc. 2 bank/agency) ▪ 20 drug rounds (four at 6am, five at 12pm, six at 6pm, and five at 10pm) ▪ Total 29 hours of observation, of which 14 hours 13 min were during drug rounds; the remainder were before and after drug rounds
Site C 18-bed adult neurological rehabilitation ward in an acute hospital of a foundation NHS trust, East Midlands	▪ Ward: 15 RN ▪ Observed nurse to patient ratio: ○ Day shift – 1:9 ○ Night shift – 1:9 ▪ Nurse participants reported fewer staff than normal during the data collection period	▪ EPMA system since July 2012, trust-wide roll out in progress at time of data collection ▪ EPMA access: one desktop computer, one laptop attached to the drug trolley, and two COWs ▪ 1 x large drug trolley ▪ Conventional metal bedside medication lockers ▪ Two nurses administered drugs to all patients together ▪ 'Opt-out' patient self-administration policy ▪ HCAs facilitated with drug administration ▪ No IV doses were prescribed (patients on this ward do not usually require IVs)	▪ 12-19 November 2012 ▪ 16 RN (inc. 3 bank/agency) ▪ 18 drug rounds (two at 6am, four at 8am, four at 12pm, five at 6pm, and three at 10pm) ▪ Total 29 hours of observation, of which 20 hours 35 min were during drug rounds; the remainder were before and after drug rounds

COW, computer on wheels; EPMA, electronic prescribing and medication administration system; inc. , including; HCA, health care assistant; IV, intravenous; RFID, radio frequency identification; RN, registered nurse

Overall, six main themes and 26 associated subthemes were identified from the framework analysis (box 6.1); examples of data coded under each can be found in appendix 28.

Box 6.1 Main themes and subthemes of factors that influenced medication safety, workflow, interruptions and distractions.

1. **Structure of the ward-based medication system and resources available**
   - 1.1 Prescribing system
   - 1.2 System for documenting medication administration
   - 1.3 Ward-based medication storage
   - 1.4 Patients' own drugs
   - 1.5 Medication ordering system
   - 1.6 Policies and guidance
2. **Medication system use in practice**
   - 2.1 Actual and potential system-related problems identified by nursing staff
   - 2.2 Problem-led temporary deviations from intended use (workarounds)
   - 2.3 Non problem-led deviations from intended use
3. **Medication safety**
   - 3.1 Patient as a medication problem alert system (for both actual and potential problems)
   - 3.2 Nurse as a defence for actual and potential medication problems
   - 3.3 Actual and potential inappropriate prescribing and prescribing errors
   - 3.4 Actual and potential strategies to increase medication safety
   - 3.5 Actual and potential medication administration errors
4. **Workflow (factors that influenced workflow)**
   - 4.1 Medication ordering, replenishing, and security
   - 4.2 Medication administration support from and to other health care professionals
   - 4.3 Staff expectations, use of prior knowledge, and information transfer
   - 4.4 Patient's clinical status, needs, and requests
   - 4.5 Shared resources required for medication administration
   - 4.6 Individual nurses' approach to medication administration tasks (order of activities)
   - 4.7 Actual and potential strategies to streamline workflow or increase efficiency
5. **Interruptions and distractions**
   - 5.1 Sources of interruptions and distractions
   - 5.2 Time and location of medication administration
   - 5.3 Nurses' role, responsibilities, and relationships
   - 5.4 Actual and potential strategies to manage interruptions and distractions
6. **Observer-related effects**
   - 6.1 Actual and potential effects of the presence of an observer on nurse/other staff/patient behaviour

Five of the six main themes were based on the initial thematic framework (figure 6.1), and the sixth was subsequently included to reflect the actual and potential effects of having an

observer on ward staff and patients' behaviour. From these, three cross-cutting themes describing the sociotechnical factors that facilitated and hindered successful drug administration were identified (each is described separately in the following sections):

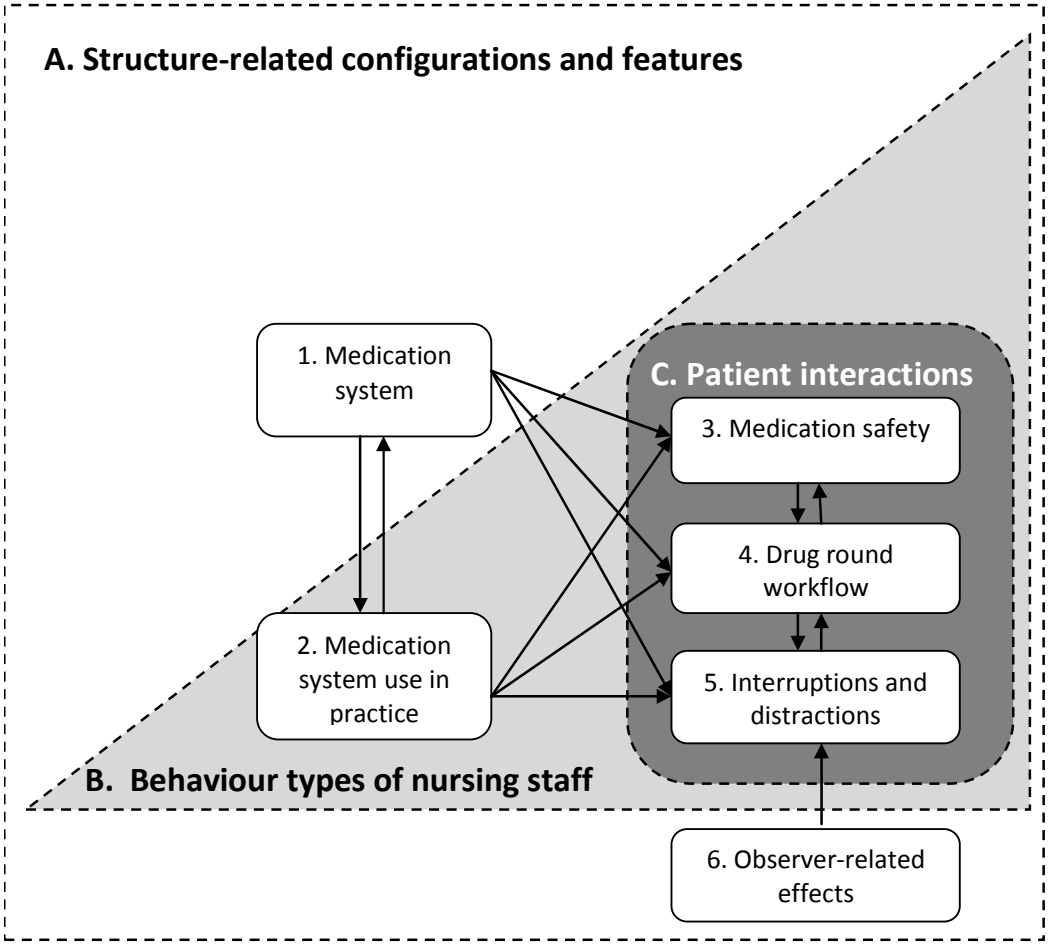
A. Structure-related configurations and features (section 6.6.2)

B. Behaviour types of nursing staff (section 6.6.3)

C. Patient interactions (section 6.6.4)

Figure 6.2 shows the three cross-cutting themes in a conceptual diagram that was developed from the initial framework in figure 6.1.

Figure 6.2 Conceptual overview of thematic factors that influence MAEs, workflow, and interruptions associated with the hospital medication administration process: framework comprises six main themes (numbered) and three cross-cutting themes (A to C)



Key
__ Main themes (1 to 6)
--- cross cutting themes (A to C)
→ Arrows indicate direction of influence between main themes

As depicted in the conceptual diagram (figure 6.2), the cross-cutting themes overlap and transverse the six main themes in different ways. 'Structure-related configurations and features' was conceptualised as the foundational theme that affected different types of nurse behaviour, which in turn, incited different types of patient interactions; each comprised components that exerted a positive and/or negative impact on medication safety, drug round workflow, interruptions and distractions. Thus, the results are next focused on these three cross-cutting themes, supported with selected examples from observation field notes and feedback from nursing staff.

6.6.2 Structure-related configurations and features

Specific configurations (location and arrangement of human and material resources) and features (characteristics, interpretability, and pre-conditions for use) of structure-related aspects (Donabedian, 2003) of the medication system acted as a physical constraint on some drug round tasks; these increased medication safety in some cases, but contributed to interruptions, distractions, impaired workflow, and medication problems in others (table 6.5, figures 6.3 to 6.5).

Table 6.5. Examples of system configurations and features associated with potentially positive and/or negative impact on medication safety, interruptions, distractions, and workflow.

	Observed potential positive effect	Observed potential negative effect
<u>System configurations</u>		
Location	• A desktop computer was near the stock cupboard for oral medicines, thus allowing nursing staff to check the EMAR on their preferred device while preparing medicines that may not be available from the drug trolley (some nurses reported problems with the mobile EPMA devices and therefore did not take it with them into the treatment room to prepare intravenous medications) (site B) • Drug trolley was kept in the treatment room and was often replenished immediately prior to and/or after the drug round (site C)	• Infusion pumps and stands were located in a separate room at one end of the ward away from the treatment room containing drugs and therefore potentially increased 'travel' for nursing staff (site A) • A few medicines (for example, nebules and pre-filled syringes) were sometimes kept on the shelf at the bottom of the drug trolley in addition to inside the drug trolley which was accessible to passers-by (sites A&B) • The day room was located some distance away from the patient bed areas which was a particular problem on this ward as some patients were mobile and often in the day room during drug rounds; thus potentially increased 'travel' and opportunities for interruptions to nursing staff (site C)
Arrangement	• Some patients kept their inhalers and creams altogether in a small plastic box on the bedside table (rather than in different locations around the bedside) which seemed to make it easier for nurses to find those drugs (sites A&C) • Medications in the drug trolley were arranged such that the front (rather than the side) of most packs were facing the nurse to aid drug identification (sites B&C) (figure 6.3)	• Some frequently used intravenous drugs (for example, paracetamol and metronidazole) were stored on the top shelves which made them less accessible than some other drugs (site A) • Some patient bedside medication lockers were positioned so that the locker opened towards the bed (rather than towards the nurse opening it) which made it more difficult for the nurse to access the contents (site C)
<u>System features</u>		
Characteristic	• The patient bedside medication locker was a removable drawer which could be moved to an alternative area while preparing medicines (for example, if there was limited space at the locker to place the drug chart or mobile EPMA device, or more than one drug was required from the bedside medication locker) (sites A&B) • Ward staff developed a standard form for documenting medication-related tasks that required follow-up after the drug round (site C)	• Drug charts were misplaced (site A) • Reported unreliability of computer tablet devices and font size too small on laptop led to nurses reporting a preference for using the desktop computer on some drug rounds. This meant that the EMAR was sometimes not used at the patient's bedside or at the drug preparation location (site B) • Nurses had to stoop to open patient bedside medication lockers (site C)
Interpretability of features	• Paper drug chart was relatively intuitive to use (site A) • Medication orders were legible on EPMA system (sites B & C)	• Drug administration code for 'patient refused' and 'patient did not require' were used interchangeably (site A) • EMAR screen did not show all or any additional information provided by pharmacy staff (site B&C)
Pre-conditions for use	• All stock cupboards were in one room which potentially facilitated medication retrieval during drug rounds (site A)	• Password and training required to use EPMA system therefore could not be used by locum staff. Instead, regular nursing staff printed out MARs for locum staff to use and transcribed medication administration documentation for them on to the EPMA system after each drug round (sites B&C)

EMAR, electronic medication administration record; EPMA, electronic prescribing and medication administration system; MAR, medication administration record

Figure 6.3 Medicines in one of the drug trolleys at site B. Medications were arranged such that the front (rather than the side) of most packs were facing the nurse to aid drug identification, retrieval, and facilitate replenishment.

Figure 6.4 Spaghetti diagram showing path of travel by a single nurse during one drug round and the potential influence of systems configuration on drug round workflow at site B (map of ward not drawn to scale). *Nurse started the drug round by logging on to the tablet computer next to the drug trolleys at 21:05, placed tablet computer on drug trolley and wheeled it to each patient starting in C-bay. Nurse went to the nurse base station area 13 times during the drug round: to look for master key to patient's bedside medication locker (2 times), to look for medicines in stock cupboard (4), to access desktop computer to view and/or sign patient medication orders (5), to take a telephone call (1), and to prepare from the controlled drugs cupboard (2). Nurse ended the drug round at the nurse base station double checking on the electronic prescribing and medication administration system that all the relevant doses had been signed. S02, site identifier code; DR022, drug round identifier code; N18, nurse identifier code; pts, patients; meds, medicines.*

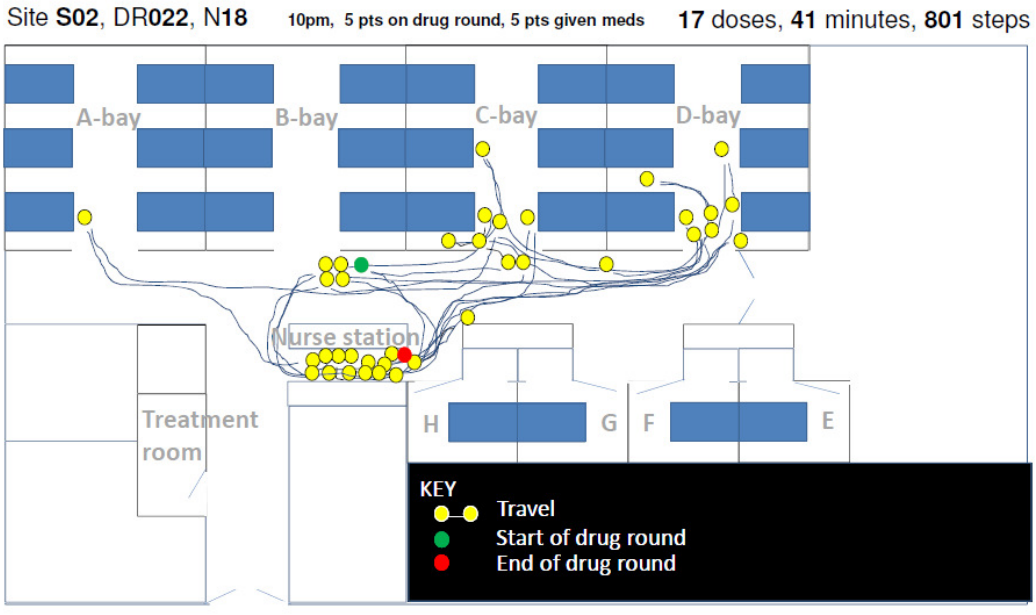
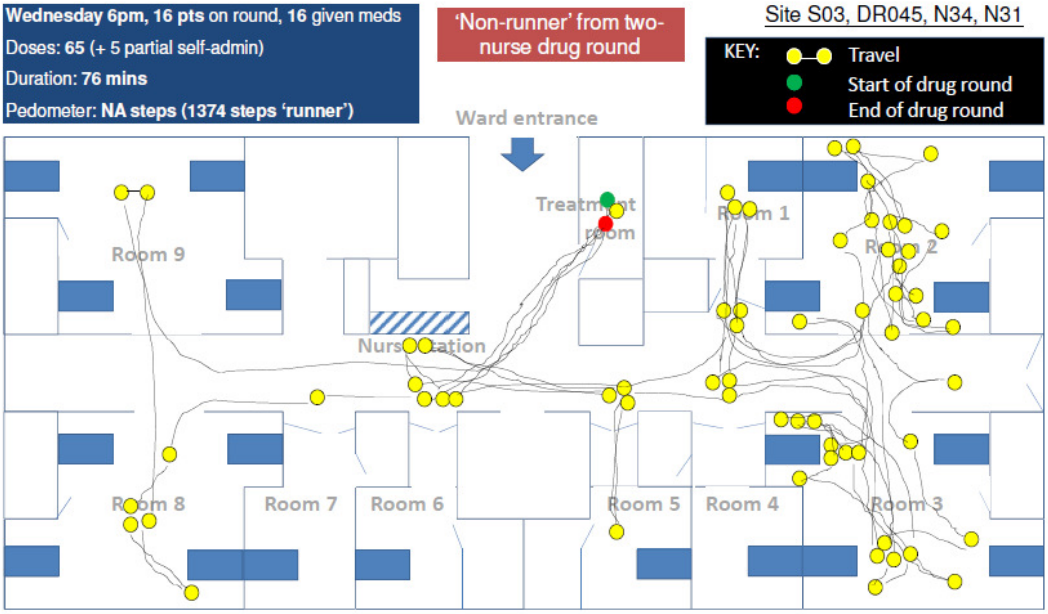


Figure 6.5 Spaghetti diagram showing path of travel by a single nurse during one drug round and the potential influence of staff configuration on drug round workflow at site C (map of ward not drawn to scale). *At site C, two nurses typically worked together on the drug round to administer medications to all patients; one nurse 'caller' and one nurse 'runner'. The map below shows the path of travel by the nurse 'caller' whom initially stayed with the drug trolley: she used the laptop attached to the drug trolley to access the patient's electronic medication administration record, called out doses to the 'runner' to retrieve medications from the bedside medication locker and prepared some doses from the drug trolley. After the doses had been prepared for the patient in room 6, the nurse caller went 'ahead' while the nurse runner remained to administer the doses; this process was repeated whenever a patient required assistance to take the medicines and led to a 'single-nurse' drug round for parts of the remaining round. During the drug round, the nurse caller went to the nurse base station twice (to retrieve patient 6 folder to check oxygen saturation and to retrieve patient 5 folder for paper warfarin medication order) and treatment room once (to retrieve medication from the fridge) during the drug round. S03, site identifier code; DR045, drug round identifier code; N34 and N31, nurse identifier codes; pts, patients; meds, medicine; NA, not applicable; self-admin, patient self-administered medications.*



Optimisation of structure-related configurations and features that negatively impacted medication safety, interruptions, distractions, and workflow were recognised by some nurses as a potential area for improvement. Some sub-optimal systems configurations and features were frequently reported by nurses as a hindrance to drug administration (table 6.5). However other sub-optimal configurations and features were not reported but revealed through observation; for example, when certain basic tasks appeared to be ergonomically challenging or awkward, the nurse seemed perplexed by the task, a deviation from policy was observed, or a more optimal configuration and/or feature was observed elsewhere on

the same ward. In general, few individuals sought to resolve the underlying structure-related problems or inefficiencies during the observed study period; in most cases, the individual seemed to have accepted the problems or inefficiencies and either worked with it, or worked around it:

> *Nurse told me she sometimes likes to put two drug trolleys together so she can prepare the medicines more easily [implied medications were not always available from one drug trolley].*
>
> (Site A, nurse with over 1 year of experience on the ward)

> *Nurse told me she preferred to use the tablet computer over the computer on wheels (COW) as she found the mouse pad tricky to use on the COW. However, she preferred to sign for medication administrations at the desktop as the tablet computer was too small.*
>
> (Site B, nurse with over 7 years of experience on the ward)

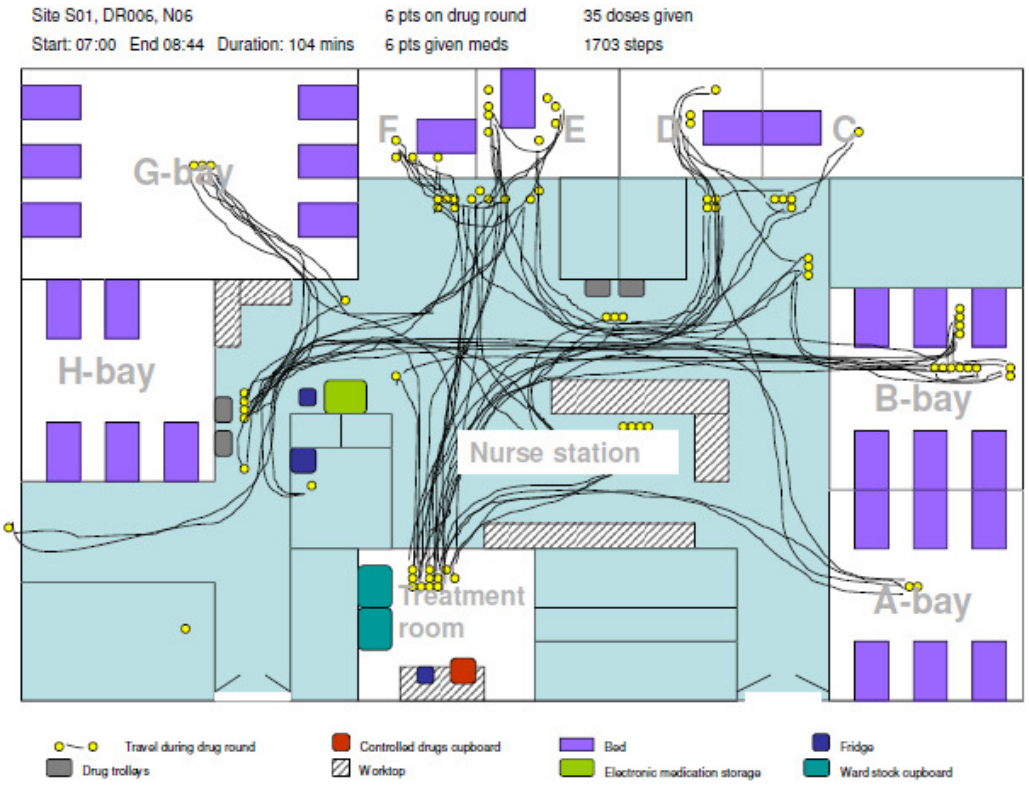
Based on individual feedback and observations, the type of action taken to manage perceived medication system related problems or inefficiencies partly depended on individual behaviour types, which are described in the next section.

6.6.3 Behaviour types of nursing staff

As illustrated in figures 6.4 and 6.5, medication administration was not a linear process; each map showed the path of travel by one nurse during a single drug round (all 27 maps can be found in appendices 29-31). In general, nurses encountered a number of drug round tasks which took them to locations other than the patient's bedside (figure 6.6): examples include nurses going to another ward to borrow medicines during and outside pharmacy opening hours, to the day room to find the patient, the treatment room for medication and equipment, the nurse base station for patient folders, other parts of the ward to speak to other health care professionals, and to the kitchen to retrieve refreshments and nutritional

supplements. Observed variation between individual approaches to drug round tasks on the same site suggests that medication administration workflow was not only influenced by structure-related configurations and features, but also by individual behaviours that appeared to be inherent and situation dependent; some of which included deviations from 'typical' practice.

Figure 6.6 Path of travel by one nurse during a morning drug round showing travel to several locations other than patients' bedside at site A (map of ward not drawn to scale). *S01, site identifier code; DR006, drug round identifier code; N06, nurse identifier code; pts, patients; meds, medicines.*



Inherent and situational behaviour types

Broadly, nurses appeared to have a general inherent tendency to be either primarily 'task focused' (main goal of drug round was to administer drugs as efficiently as possible), or 'patient-interaction focused' (drug round was more of an opportunity for the nurse to interact with their patients in addition to administering medications) during the drug round.

Both inherent behavioural types potentially increased and decreased aspects of medication safety, but differed in their general approach to drug round workflow, interruptions, and distractions. Task-focused individuals generally used a more streamlined workflow and tended to react minimally to interruptions and distractions. In contrast, patient-interaction focused individuals adopted a relatively less streamlined workflow, and were generally more proactive in response to interruptions and distractions. Excluding urgent tasks, individuals who were primarily task focused generally carried out few non-medication administration related tasks during the drug round; when these tasks were identified during the drug round, the nurse either deferred it to the end of the drug round, or carried out the task when another task took the nurse to a convenient location to carry out multiple tasks. Conversely, individuals who were relatively more patient-interaction focused, appeared to proactively 'encourage' communication with patients and/or other staff during the drug round; the patient-interaction focused individuals either multi-tasked, carried out the non-medication administration related task shortly after they completed the primary task, or stopped the primary task to carry out the non-medication administration related task.

In general, the behaviour types exhibited were not fixed; individuals appeared to shift from one to another, depending on the needs of the patient, the medication system being used at the time, the task being carried out, and other situational circumstances at the time. Examples of nurse behaviour types are provided in box 6.2.

Box 6.2 Examples of inherent behavioural tendencies and associated influences on how systems were utilised, and how medication administration related problems, interruptions, distractions, and workflow were managed.

Task focused

- Nurse deferred a task for later. As the nurse was at patient C3's bedside about to move on with the drug round, patient C4 interrupted and asked the nurse to remove her Venflon®. Brief discussion, nurse explained that she still had medications to give and will come back to see her later (site B)
- Nurse grouped some tasks to do together rather than stop what they were doing. Whilst the nurse was preparing ketamine in the treatment room, she also picked up a box of tinzaparin and then some plastic cups (these were needed in the drug round earlier) from the other drug trolley outside a patient bay before going back to patient G1 to administer the ketamine, then prepared the oral morphine sulphate solution, gave to the patient, then paracetamol, and then administered the tinzaparin to the patient (site A)
- Nurse re-ordered some tasks to increase efficiency. Patient was fast asleep and was due medication, N28 told N36 that she'll "sign for it now so all the paperwork is done", wrote a reminder to administer medications on a pre-printed job's list form and said she will give the medications to the patient when he is awake (site C)

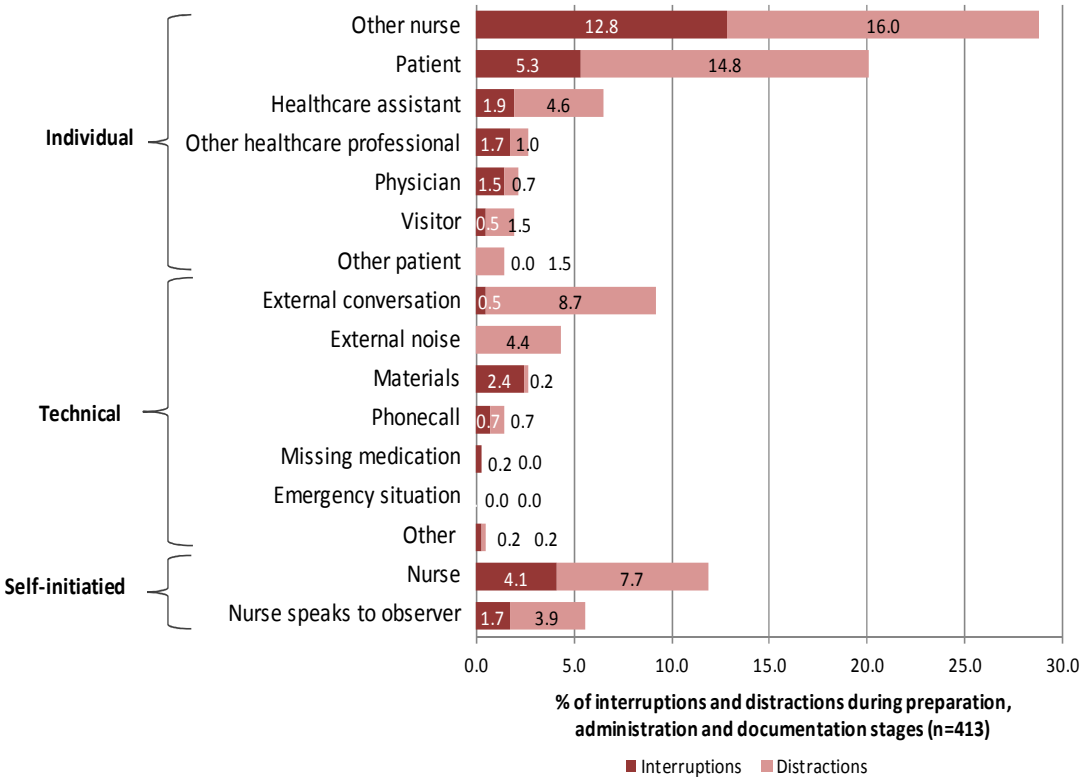
Patient-interaction focused

- Nurse prioritised a non-drug round related activity over the drug round. N12 talked to the patient as she was administering slow IV bolus of co-amoxiclav. Later saw another nurse helping patient G1 with his VAC dressing, N12 went to help, took about 20 min for N12 to go to TR, draw up saline flush, go back to G1 to try to unblock tube, got interrupted by another nurse several times, decided to change a vacuum-assisted closure dressing, prepared dressing trolley and changed dressing before returning to the drug round (site A)
- Nurse dealt with a patient's query straight away. Patient asked the nurse about her aspirin, said she hasn't taken it today. Nurse stopped what she was doing to talk to the patient. Patient said nurse last night gave her an injection to replace the aspirin, nurse confirmed that she will also give the injection (site B)

Given that nurses themselves were the third most common source of interruptions and distractions (figure 6.7), it is therefore likely that individuals' inherent tendencies may also influence the potential for MAEs. However, the 'direction' of influence (positive or negative) on drug round workflow and MAEs also depended on the medication systems being used and the task that was being carried out at the time (situation dependent). Consistent with the study by Pape (2003), 'other nurses' were the most common source of interruptions and distractions to the individual on the drug round, and the other nurses' tendency to interrupt or not (as well as health care assistants and other individuals on the ward) also appeared to

be partly influenced by the individual on the drug round. Lastly, both the task-focused and patient-interaction focused behaviours were associated with some structure-based deviant local practices which had the potential to increase and decrease medication safety; these are described in the next section.

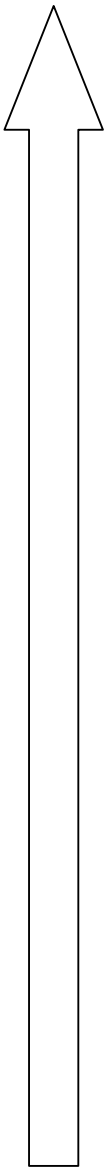
Figure 6.7 Sources of interruptions and distractions during non-intravenous drug rounds (% of a total of 413 interruptions and distractions observed at the preparation, administration, and documentation stages of the drug round). *Median 5.5 interruptions per drug round hour, range 0 to 24; median 9.6 distractions per drug round hour, range 0 to 30; median 15.5 interruptions and distractions combined per drug round hour.*



Structure-related behaviour and deviations from 'typical' local practices

Based on feedback from nursing staff and observations, a range of intentional deviant practices related to the 'structure' aspects of the medication systems were identified. Broadly, intentional non-conformer behaviour appeared to be of three main overlapping types: efficiency seeking, multi-tasking, and experienced practice-overriding. Examples of each behavioural tendency observed and reported are listed in figure 6.8.

Figure 6.8 Different types of non-conformer behaviours with examples from individual nurse feedback and observations. Each type of non-conformer behaviour and the potential relationship to the perceived level of difficulty of structure based change. *IV, intravenous;*



Perceived structure related problem or inefficiency was considered difficult to change or not changeable

Perceived system related problem or inefficiency was considered easily changed

Experienced over-riders

- "You'll notice I'm also not checking wristbands because all the patients have been here for 100 years" (site C)
- Nurses noted that they were supposed to wear a 'do not disturb tabard' during drug rounds but did not. Reasons reported include: they did not think it worked (site A), raised concern about the cleanliness of tabards (site C), and found it made them too hot (site C)
- Nurse rescheduled enoxaparin 18:00 to 22:00 during the drug round as found out that the pt last had the dose at 14:00. Enoxaparin was prescribed twice daily (site B)
- Nurse found out from patient that he takes atenolol in the evening, went through other medicines, rescheduled atenolol and sitigliptin to 18:00 (site B)

Multi-taskers

- Nurses frequently used the desktop computers at the nurse base station during drug rounds to access patients' medication administration records and remained logged into the system during drug preparation and administration: "please nobody log me off, I'm doing the meds" (site B)

Efficiency seekers

- Instead of taking the drug trolley to the patients as she did previously, this time the nurse started by retrieving the relevant patients' drug charts (two were at the bedside as expected, one was later found near an empty bed in the same bay), then proceeded to prepare doses from two adjacent drug trolleys parked at the nurse base station. N08 later told me that she sometimes likes to put the drug trolleys together so she can prepare the medicines more easily (site A)
- Nurse put IV paracetamol tray in the drug trolley, deliberately left it there after 10pm drug round in preparation for the morning round (site B)
- Nurse asked the patient if he applied his own creams, patient confirmed that he does, nurse left 2xcreams at the bedside for the patient to self-administer (patient is not on self-administration scheme), nurse signed for administration (looks like she administered them). (site C)

In general, efficiency seekers tended to deviate from typical local practice when they had perceived an inefficiency within the system, but also a potential solution to the problem; sometimes the deviant practice observed was part of an established tried-and-tested routine for the individual and at other times, it was more spontaneous. By contrast, multi-taskers

also sought to maximise efficiency, but the 'solution' involved carrying out multiple tasks concurrently to the perceived problem rather than focusing on resolving the problem before moving on to the next task. Multi-tasking behaviour was frequently observed in individuals who were in charge of the ward during observed drug rounds, and also observed in individuals that were relatively experienced with typical local practices irrespective of their management role during the shift. The experienced practice over-riders behaviour type was generally observed when the individual encountered a known recurring problem or inefficiency, and believed that in their experience, the resultant deviant practice posed no additional risk to the patient.

Based on the systems and tasks observed that appeared to trigger each of the three non-conformer behavioural types, a potential relationship with perceived level of flexibility for structure change was observed. At one end of the 'flexibility for change' spectrum were problems and inefficiencies that were perceived to be easily overcome by adopting a different process, at the other end were problems and inefficiencies that were perceived as being more 'difficult' to change or could not be changed, and therefore individuals used their experience to override them (figure 6.8). Relating to the latter, an alternative behaviour type was also observed, 'critically conforming'; individuals with this behaviour identified a perceived problem or inefficiency but would persist (rather than override) the task:

> *Two nurses discussed the problem of night staff giving morning meds at 6am. They did not think it was a good idea as it is too early and not practical to do observations. Thought day staff should do drug rounds as think there is not much to do in the morning.*
>
> *(Site A)*

6.6.4 Patient interactions

As depicted in figure 6.2, interactions between patients and nursing staff resulted in an observable effect on medication safety and drug round workflow, with patients additionally being the second most common source of interruptions and distractions during drug rounds (figure 6.7). Nurse-patient interactions potentially increased medication safety in some situations, and potentially reduced medication safety in others. Consistent with the literature (Britten 2009), patients sometimes acted as a defence barrier to medication error. Specifically, the current study found three manifestations of the patient defence barrier (table 6.6).

While patient interactions primarily related to relationships between nursing staff and the patient, a number of systems-related influences on these relationships were also observed: for example, nurses typically did not take the computer on wheels (sites B and C) or drug trolley (all sites) into patient side rooms, and individuals generally relied on their memory and/or brought medications out of the room to prepare doses thus potentially reducing patient involvement. Patient involvement was also important not only as a potential defence barrier for MAEs but also to optimise their treatment. The dose omission rate due to therapeutic reasons was 11.4% of OEs, much of which involved direct nurse-patient interaction during the drug round.

Table 6.6 Three observed manifestations of the patient defence barrier	
	Examples
Patients helped nurses to identify potential prescribing errors	• Nurse noticed on the drug chart that the patient had not received tinzaparin recently (there were two doses crossed off and one blank administration box), she asked the patient "do you know of any reason why you haven't been given the tinzaparin?" "I get it on dialysis" replied the patient. Tinzaparin had been prescribed for once daily administration and there was no documentation on the drug chart to indicate that the patient was to receive this on dialysis days only. (site A) • Nurse told the patient what she was giving (included naproxen and omeprazole); patient explained he takes both at night: “only take it at night” “not morning?” “only take it at night” “ah they prescribed it for this morning…..I don’t know why [they] prescribed it for morning” explained to patient that she did not give these last night and so patient took the medications at the morning drug round. (site B) • Medication order did not specify which eye(s) the eye drop was to be applied. Nurse asked the patient, "your eye drops, do we do it for you or you do it?" "You do it" "Is it both of the eyes?" Patient confirmed it was for the right eye, nurse administered it to the patient’s right eye (site A) • Patient highlighted discrepancy in pregabalin dose, told the nurse it should be 250mg twice a day, but it was prescribed as 100mg twice a day, nurse documented this and talked to patient about changes in medications (site C)
Patients helped nurses to identify potential medication administration problems	• Patient told the nurse she could not break up the cocodamol and therefore did not take the dose that was given to her in the previous drug round. The dose had been signed for but was not actually taken. Nurse was aware, helped patient crush tablets by using two spoons (could not find tablet crusher on the ward). Documented current dose not given (site B) • Nurse prepared a dose of metronidazole then realised that the medication order had been stopped on the chart and discarded the dose at the drug trolley (956-958). Metformin dose prescribed was 500mg - 1g on chart and prescriber had written “1g OM” in additional section of chart for metformin. Nurse had prepared 500mg and given to patient but later corrected it when prompted by the patient and gave 1g in total. (site A)
Patient acted as a double-checker	• Nurse went straight to the patient’s bedside medication locker to retrieve the patient’s own gliclazide, omeprazole, metronidazole and pioglitazone. During this time, the patient asked “is it metformin?” Patient told the nurse that the metformin was in the same packet as the gliclazide (site B) • Nurse prepped meds at the drug trolley and then took over to the patient, patient asked for “diclofenac”. Nurse had not prepared this (site C)

6.6.5 Practices observed that potentially increased medication safety

A number of practices were observed that potentially contributed to increased medication safety, streamlined drug round workflow, and reduced interruptions and distractions. These are listed in table 6.7.

Table 6.7 Practices that potentially contributed to increased medication safety, better workflow, reduction in interruptions and/or distractions on the sites observed.	
To increase medication safety	• Ward staff developed a standard form for documenting medication-related tasks that required follow-up after the drug round (site C) • Two nurses went through each patient's drug chart during handover to check for missed doses and/or queries with the patient's medication (site A)
To streamline workflow	• Nurse retrieved additional medications from the stock cupboard prior to starting the drug round (all sites) • Fridge items were placed in the drug trolley prior to starting the drug round (site C) • Nurse checked EPMA at the nurse station prior to starting lunchtime drug round for doses that were due. Nurse expected very few doses and did not use drug trolley on the drug round but prepared medications at the nurse station from the stock cupboard (site B) • Nurse asked the patients whether or not they wanted painkillers some time prior to the drug round and therefore knew in advance which patients needed painkillers and was able to go to those patients specifically during the lunchtime drug round (site B) • Drug trolley was kept in treatment room and was often replenished immediately prior to and or after the drug round (site C) • Medications in the drug trolley were arranged such that the front (rather than the side) of most packs were facing the nurse to aid identification (sites B and C) • Some patients kept their bedside medications together in a box which seemed to make it easier for nursing staff to find medications not stored in the bedside medication locker, for example, creams and inhalers (site C) • HCAs helped patients to take their medicines after the nurse had dispensed the relevant doses, this included nebulisers, application of creams (site C) • Nurse reconstituted multiple doses of IV Tazocin® (piperacillin and tazobactam) medications as knew each vial would take a long time to dissolve (site A)
To reduce interruptions and distractions	• Nurses sometimes wore a 'do not disturb' tabard (site C) • Ward staff placed a 'ward screen' at the entrance of a bay in which patients were being washed, this discouraged interruptions to anyone inside the bay (site C)
HCA, health care assistants; HCP, health care professionals; MAR, medication administration record;	

6.7 Discussion

6.7.1 Main findings

Overall, six major themes, 26 associated subthemes, and three cross-cutting themes were conceptualised to summarise the systems based effects on the safety of medication administration. The three cross-cutting themes were 'structure-related configurations and

features', 'behaviour types of nursing staff', and 'patient-interactions'. Consistent with the previous research described elsewhere in this thesis, variations in hospital ward medication systems exist but much more subtle variations than previously reported were identified and described in the present study. Subtle structure-related variations in available resources, such as their specific location, arrangement, characteristics, features, and pre-conditions for use, appeared to influence individual behaviour and patient interactions, with some notable positive and negative unintentional consequences on medication safety.

Based on the study findings, a number of systems-related nurse behaviour types were identified. A focus on deviant behaviour from typical local practice led to a proposed relationship between the level of perceived difficulty for systems change and the type of non-conformer behaviour exhibited by individuals during specific medication tasks. Analysis of deviant behaviour was based on nurses' feedback during the observations and was therefore primarily associated with structure-based inefficiencies only and other reasons for deviant behaviour was not explored. Nonetheless, the analysis of nurse behaviour types showed that potential latent conditions for MAEs can be identified by examining non-conformity to typical local practices.

6.7.2 Implications for practice

Taking proactive measures to identify local and organisational conditions that need correction has been advocated as a navigational aid to help drive development of organisational resistance to operational hazards in health care (Carthey et al., 2001). Findings from the current study included identifying a number of practices that potentially contributed to increased medication safety (table 6.7). Some of these practices were reported by staff, some were not; this emphasises benefits of an observational approach to 'looking' and 'seeing' practices in natural settings. The practices presented are intended to

stimulate review of existing systems and processes in a different way than previously carried out and are not necessarily suitable for every setting. There may be differences in other settings that would result in some different sociotechnical interactions that might not have been observed on the three study sites. However, the main cross-cutting themes were developed from observation and analysis across a wide range of nursing staff and therefore the concepts are likely to be more transferable to other hospital ward settings than individual practices observed. More importantly, recognising the concepts such as sub-optimal structure-related aspects of the medication system need not be restricted to researchers, managers, or specialists. As the current study shows, many sub-optimal structure-related aspects were already known to at least one individual who worked within, or were exposed to, the structure. This included patients in addition to ward staff. Increasing patient and staff engagement in medication safety may therefore be an important method to increase medication safety. Furthermore, many relatively cost-neutral and 'low-tech' suggestions were identified. Additionally, the thematic framework in figure 6.2 may be transformed into a checklist to facilitate identification of structure-related areas for further optimisation.

6.7.3 Comparison of quantitative findings with previous research

The MAE rate for non-IV OEs identified in the present study (2.7%) was significantly lower than previously reported in a recent systematic literature review (5.6%; 95% CI 4.6-6.7%),(chapter three; M^{c}Leod et al., 2013). This was unexpected as the definitions and methods used were comparable to the studies that were included in the review. However, the lower MAE rate may be due to the relatively small sample of non-IV OEs observed in the present study (445 non-IV OEs compared to the 842-3576 non-IV OEs included in previous studies) (chapter three; M^{c}Leod et al., 2013).

The present study identified a median rate of 5.5 interruptions per drug round hour and 9.6 distractions per drug round hour. The former is similar to the 6.7 interruptions per hour reported in the literature review by Biron et al (2009), which was based on a total of 2,622 interruptions observed over 402.5 hours during medication administration by nurses in 14 studies. The included studies were conducted in a range of acute care settings. However, the definition for an interruption varied between studies (Biron et al., 2009). Although the specific definitions were not described, Biron et al (2009) reported that different definitions were associated with a measurable difference on reported interruption rates, and that some used "interruptions" and "distractions" interchangeably. Thus, it was unclear whether or not the interruption rate reported by Biron et al (2009) included 'distractions', which was defined separately in the present study. Combining interruptions and distractions resulted in a total of 15.5 'interruptions and distractions' per drug round hour, which is higher than the 6.7 interruption rate by Biron et al (2009).

6.7.4 Strengths and limitations

A strength of the current study was inclusion of multiple sites that used distinctly different medication systems; this sampling approach enabled the findings to reflect the diversity of 'typical' and relatively 'atypical' local practices used by nurse participants of a range of experience to administer medications. By using an ethnographic approach rather than self-report, a number of 'real-world' practices, both obvious and subtle, were identified from the study sites were described. Furthermore, feedback from nursing staff about the observation experience was generally positive which suggests the presence of the observer was not perceived to be a problem. Some nurses and HCAs seemed particularly interested in the study and were extremely helpful and receptive towards the researcher. Staff were generally quite open about their opinions of the systems relating to medication administration and provided invaluable additional insights into their rationale for the approach they took during

drug rounds. Overall, the mixed-methods approach not only enabled triangulation of the main findings, but the quantitative data using methods and definitions from the literature allowed for more objective comparisons to be made with previous studies in this area.

Sociotechnical interactions are complex; there are multiple interconnecting systems and processes that are not always apparent. A limitation of the current study is that it only focused on those interactions related to medication systems used by nursing staff to administer medications to hospital inpatients, and thus did not consider the wider impact of structure optimisation on the work processes of other health care professionals. In addition, other physical environmental factors such as noise, lighting etc. that have been associated with nursing errors and efficiency (Chaudhury et al., 2009) were also not explored as these were not the main focus of the current study. Additionally, findings from the interruptions and distractions recorded in the current study indicate the presence of the observer had a measurable influence on nurse behaviour during drug rounds; this may have potentially influenced MAE rates but previous research suggests that this risk is low provided that the observer was discreet, non-judgemental, and tactful in their approach to observations (Barker & McConnell, 1962; Dean & Barber, 2001). However the overall percentage of observer-related interruptions and distractions were substantially less than those from patients despite the observer's continued presence, suggesting that any observer effects were potentially minimal but this cannot be confirmed. Finally, another potential limitation was that data were collected by one observer. Although the potential risk of observer bias was highlighted earlier as a potential problem, and subsequent efforts were made to maintain a balance between objectivity and subjectivity, the data collection and analysis are limited by the beliefs and experience of the observer.

6.7.5 Future research

The findings of the current study have touched on the systems potential to influence behaviour and also the complex sociotechnical relationship on nurses' behaviour and the potential for increasing medication safety. Further research is required to better understand how safety-related behaviours may be proactively developed to identify latent conditions for MAEs, and to develop a method for identifying and monitoring these latent conditions to pro-actively prevent or ameliorate MAEs, ideally incorporating a range of stakeholders including patients. Other potential future research directions include:

- Evaluate the use of the thematic framework based checklist as a tool for identifying and monitoring structure-related configurations and features that can be further optimised in a range of settings
- Explore the effects of interventions to reduce time spent on non-urgent, non-medication administration related tasks during drug rounds

6.8 Conclusion

Overall, a number of subtle structure variations in available resources appear to influence individual behaviour and patient interactions, with some notable positive and negative unintentional consequences on medication safety. Individuals (including patients) within different medication systems were found to be a good source for identifying actual and potential medication related problems and therefore potential targets for structure optimisation; some were intentional and revealed by studying deviant practices by nursing staff, while others were seemingly unintentional and were identified by using an ethnographic observational approach in this study. Further research is required to better understand how potential underlying systems-based problems may be better identified and rectified to increase medication safety.

Chapter 7. Overall discussion

Since starting the research presented in this thesis, medication errors have continued to be a major patient safety concern in the UK. A review of 526,186 medication incident reports to the NHS NRLS between January 2005 and December 2010 has revealed that 822 (0.9%) were associated with patient death or severe harm (Cousins et al., 2012). Separately, a study involving a retrospective review of 1,000 adults who died in 10 acute hospitals in England identified drug or fluid-related problems as the third largest cause (21%) of preventable deaths (Hogan et al., 2012). Additionally, the problem of dose omissions was highlighted in the recent high-profile public inquiry report on the failings identified at Mid Staffordshire NHS Foundation Trust (Francis, 2013a; 2013b; 2013c). Medication errors pose a threat to all three dimensions of quality care (Department of Health, 2008): patient safety, clinical effectiveness, and patient experience, and therefore efforts to reduce medication errors continue to be a national priority in the UK (Cousins et al., 2012).

Errors at the medication administration stage have continued to hit the national headlines (BBC, 2012a; 2012b; Britten, 2011; Barrow, 2012) with emphasis often attributed to human error at the 'sharp end'. However, evidence suggests that human errors at the 'blunt end' contributes to poor organisational systems, poorly designed work environments, and inadequate defence barriers, and thus also play a major role in the occurrence of MAEs

(O'Shea, 1999; Armitage & Knapman, 2003; Carlton & Blegen, 2006; Mcbride-Henry, 2006; Fry & Dacey, 2007; Hughes & Blegen, 2008; Brady et al., 2009; Chaudhury et al., 2009).

There is much that health care can learn from the systems approach used to evaluate causes of major accidents in high-risk industries such as nuclear power and aviation (Kohn et al., 1999; Department of Health, 2000a; J. Reason, 1995). Unfortunately, complex interactions associated with medication administration processes and the small window of opportunity for detecting MAEs before medicines are administered to the patient limit the transferability of some industry-based approaches for systems improvement; this has been a challenge for developing effective systems-based intervention to reduce MAEs (chapter one). Furthermore, as health care systems and processes have generally evolved rather than being designed, it was suspected that variations exist within and between hospitals in the types of medication systems used to support medication administration. Such potential variations pose an additional challenge for developing interventions that would be useful across the wider NHS. Consequently, the overall aim of this thesis was to explore variations in hospital medication systems used to support medication administration and their effects on the safety of medication administration.

In considering the methodological approach for this research, it became apparent that the core tasks and defence barriers associated with medication administration should initially be considered as a 'whole', rather than in isolation; this was to identify potential area(s) for exploring systems variation. Additionally, a gap in the literature on methodological variations between quantitative MAE studies and their effects on reported MAE rates was identified, which warranted investigation to maximise transferability and interpretability of MAE rates. Separately, exploration of the extent of variations in hospital medication systems led to identification of a gap in the knowledge of how different ward-based medication storage systems were used to retrieve medications successfully. This then led to further examination

of systems-based factors and their effects on medication safety, workflow, interruptions, and distractions. Overall, five main research questions were identified for investigation in this thesis:

1. What are the main tasks and defence barriers associated with medication administration to hospital inpatients in the NHS? (chapter two)
2. How do methodological variations between studies affect reported MAE rates in UK NHS hospitals? (chapter three)
3. What variations exist (if any) in the types of medication systems used by staff in NHS hospitals to obtain, store, and administer medication for inpatient use? (chapter four)
4. What variations exist (if any) in the types of ward-based medication storage and transport systems used by staff to retrieve medications for administration on general medical and surgical wards within one acute NHS trust? (chapter five)
5. What systems-related factors facilitate and/or hinder safe medication administration in NHS hospitals? (chapter six)

A summary of the main findings in relation to these five research questions is next discussed, followed by limitations, implications for practice, and future research.

7.1 Summary of main findings

7.1.1 Core tasks and defence barriers associated with medication administration to hospital inpatients in the NHS

The first empirical study in this thesis identified five core tasks associated with medication administration to hospital inpatients: (1) checking a patient's identity prior to administration, (2) administering a dose and not omitting it due to drug not being available, (3) preparing and administering a dose without error, (4) observing a patient take their medications, and (5) documenting of administration or reason for non-administration. By combining these five core tasks with timeliness of medication administration, an overall quality filter of medication

was produced which revealed that 84.6% of doses were not administered according to the six standards of good practice. An MAE rate of 4.3% for non-IV OEs was also identified. Overall, four problem areas associated with medication administration were as follows: (1) there were discrepancies between prescribed time, scheduled drug round time, and actual drug round times, which suggests an underlying latent condition leading to 'wrong time' errors, (2) the patient's identity was also not always confirmed prior to administration, which indicates an inadequately used defence barrier, (3) medication administration documentation was not always accurate, which indicates an active failure that may potentially transform into a latent condition for further MAEs, and (4) doses were not always available from the patient's bedside medication locker or bedside area (no drug trolleys were used on the study site), which suggests that the ward-based medication storage system was potentially inefficient and may be considered to be a latent organisational failure for MAEs. Thus, the findings from this study highlight the importance of considering MAEs within the context of systems and processes associated with medication preparation and administration. In particular, the study revealed that 11.3% of doses were not available from the patient's bedside medication locker or patient bedside area, but only 2.6% of all doses were actually omitted. The former suggests the presence of a potential weakness in the ward-based medication storage system, and the latter suggests that nurse may be acting as a 'buffer' to counteract potential systems-based error-producing conditions. Consequently, the findings from this study led to the conception of further studies described in subsequent chapters.

7.1.2 Methodological variation and their effects on reported MAE rates

A systematic literature review was conducted to summarise the methodological variations in UK MAE studies and to evaluate their effects on reported MAE rates. Overall, three MAE definitions, 44 MAE subcategories, and four different denominators used across 16 UK-based observational studies were identified. These illustrated the extent of methodological

variations that exist even within one country. A novel meta-analysis of MAE rates was carried out based on meta-analysis methods used for experimental studies (Neyeloff et al., 2012). The calculations revealed that overall adult MAE rates were 5.6% for non-IV OEs (95% CI 4.6-6.7%), and 35% for IV OEs (95% CI 2-68%) in UK NHS hospitals. The calculations accounted for the sample size of included studies and also produced a statistic for assessing the degree of heterogeneity between included studies; medication error rates have not previously been quantified in this way (Lewis et al., 2009; Ghaleb et al., 2006). In addition, a number of methodological effects on MAE rates were quantified. Most notably, IV doses were estimated to be five times more likely to be associated with an MAE than non-IV doses (OR 5.1; 95% CI 3.5-7.5). In general, the findings emphasised the importance of methodological considerations when designing, reporting, and interpreting quantitative studies of MAEs and included reporting suggestions for future studies to facilitate consistency, interpretation, transparency, and comparability. The review also confirmed that dose omission was the most common MAE subcategory reported for non-IV doses and that omissions due to drug being unavailable were common (accounting for 52-67% for non-IV dose omissions). Overall, the findings support some inferences made by other researchers on the presence of methodological variations (Ferner, 2009; Ghaleb et al., 2006) and also contributed additional knowledge on the potential effects of these variations on reported MAE rates.

7.1.3 Similarities and variations in medication systems in English NHS hospitals

In the first national study of hospital medication systems in the English NHS, a number of systems were identified that were in use; the majority of hospitals used paper-based prescribing (87% of respondent hospitals), patient bedside medication lockers (92%), ward stock (94%), PODs (89%), and OSD supplies (85%). These findings provide an important context for those seeking to develop and prioritise systems based interventions to reduce

MAEs that would be applicable across the NHS. Additionally, a number of other system variations were also identified, particularly related to the transport of medicines during non-IV drug rounds and whether or not non-OSD supplies were used for inpatients. These findings highlight potential areas for further exploration to examine the advantages and disadvantages of these different variations, and therefore inform future developments in their design, application, and/or implementation. For example, while it was suspected that variations between hospitals existed, it was more surprising to find that only 59% of hospitals used drug trolleys on the majority of their wards; published descriptions of UK NHS hospital drug distribution systems suggest that drug trolleys were previously standard practice on hospital inpatient wards (Dean et al., 1995; Brock & Franklin 2007). Similarly, the reduction in use of non-OSD supplies to only 50% of hospitals was also unexpected as their use was once standard practice. The prevalence of a number of key medication administration related policies and guidance were also identified. In particular, 85% of hospitals had a double-checking policy for IV administrations and 58% for specific drugs or groups of drugs. Furthermore, a number of local initiatives to improve safety and efficiency of medication supply, storage, and administration were reported by 32 of 100 respondents. Overall, findings from the national survey have contributed to addressing the knowledge gap on the extent of medication systems variation that exists in English NHS hospitals. The findings provide information that can be used facilitate the development of potential interventions to reduce MAEs that are applicable across the NHS.

7.1.4 Variations in medication storage and transport systems used during non-IV drug rounds between hospitals, within hospitals, and within the same ward

An observational study that focused on the medication storage systems used by nursing staff to retrieve non-IV drugs led to the identification of a range of 'temporary drug trolley'

solutions that were used even within a single NHS trust with the same policies and guidance. Overall, one in nine doses was searched for by nursing staff in more than one location, supporting the inference in chapter two that medication storage facilities may be inefficient for dose retrieval during drug rounds. However, exploratory analysis suggested that no single type of medication storage was associated with significantly higher dose retrieval rate than other storage types. Furthermore, the study also found that nurses did not search for doses in the medication storage locations consistently. Instead, some nurses appeared to have prior expectations about where the drug should be located and accessed those areas first, and/or retrieved all medications from the patient's bedside locker, and/or placed these on the drug trolley or temporary drug trolley solution to minimise walking back and forth. Individual practice variation even on the same ward where nurses are working within the same environmental conditions suggested that a more in depth investigation was needed into how nurses use the systems available to them.

7.1.5 Systems factors that facilitate and/or hinder successful drug administration in NHS hospitals

Building on the findings on the national, local, and individual variations associated with the use of medication storage and transport systems during non-IV drug rounds, an ethnographic study was conducted at three different hospitals, each using different medication systems. Subtle structure-related variations in available resources, such as their specific location, arrangement, characteristics, and pre-conditions for use, appeared to influence individual nurse behaviour and patient interactions that had not been previously reported. While some structure-related variations may have contributed to medication-related problems, different nurse behaviour types were also apparent; these were conceptualised to describe their potential contribution to medication safety, drug round workflow, and patient interactions. Analysis of nurse behaviour types showed that potential latent conditions for MAEs can be

identified by examining non-conformity to typical local practices. Patients were also identified as a defence barrier for preventing MAEs, but this was also partly influenced by how individual nurses used the medication systems during the drug round, and how the systems were configured. Overall, the findings from this study suggest that understanding potential systems based effects on MAEs is made more complex by the variation in sociotechnical interactions that exist in practice. Research is required to better understand how safety-related behaviours and culture may be developed to increase medication safety.

7.2 Main limitations

This section summarises the main limitations across the individual studies. In this thesis, a number of systems and process based variations associated with medication administration in NHS hospitals were measured and their potential effects on the safety of medication have been described. However, there were also other human factors that were not measured because there was a practical limit to the number of variables that could be measured at any one time. These include: (1) environmental factors such as levels of light, noise, temperature, (2) individual factors such as stress, fatigue, knowledge, and (3) some organisational factors such as individual shift patterns. Instead, the systems and processes that were investigated were identified from the findings in each consecutive study, with subsequent focus on ward-based medication storage and transport system for several reasons. First, ward-based medication storage and transport is an essential component of the systems used to support timely and successful dose retrieval; consequently ward-based medication storage and transport have the potential to substantially affect the frequency of 'wrong time' errors and dose omissions, which are the two most common subcategories of MAEs for non-IV doses (chapter three). Second, an effective ward-based medication storage and transport system may reduce interruptions to nurses on the drug round (and therefore the risk of MAEs) by minimising excess travel for drug retrieval. Third, there appeared to be many individual, as

well as inter- and intra-hospital, variation in the types of medication storage and transport used across the NHS which has not been previously described, and therefore warranted further investigation.

Related to the limitations of measurement was that exploratory comparisons of MAE rates associated with different ward-based medication storage systems were not adjusted for potential confounding factors such as individual nurse participant variation in skills and knowledge. To do so would require a much larger sample than that required for the primary objective of the medication storage study (chapter five), which was to explore intra- and inter-hospital variation in where medications were retrieved from during drug rounds.

Another limitation was that clinical significance of errors was not assessed; this was related to the scope of individual studies but could have been conducted using a method such as the validated method by Dean and Barber (1999). Additionally, the thesis was generally focused on non-IV administrations as these were most likely to be influenced by systems relating to medication storage; further research is required to explore the effects of systems variation on IV administrations. Similarly, only medications administered by nursing staff were considered in this thesis as this is the main group of staff who administer medications in hospitals; it is therefore unknown how the same systems may or may not affect other health care professionals and patients who may be involved in drug administration. Finally, despite every effort to minimise the potential for observer bias, the presence of an observer was found to have some effects on nurse behaviour (chapters two, five, and six); however there was no indication that this significantly influenced MAEs or other relevant findings. In most cases, there was only one observer (MM) which may also contribute to potential observer bias, but this was considered to be limited based on the substantial inter-observer reliability identified in chapter five, and agreement with a second independent researcher in the framework analysis (chapter six).

7.3 Implications for practice

7.3.1 Tackling MAEs in hospitals – tackling the problem while blindfolded?

Since the publication of key national reports in the UK and worldwide (Kohn et al., 1999; Department of Health, 2000a; Australian Council for Safety and Quality in Health Care, 2002), health care policy makers and researchers worldwide have made several attempts to adapt strategies from high-risk industries such as aviation and nuclear power, among others, to analyse and reduce risk (Reason 1995; Vincent et al., 1998). In drawing comparisons with high-risk industries, it has become apparent that the prevalence of errors and preventable patient harm in health care have changed little over the years (Vincent et al., 2008, chapter three of this thesis), and would be considered alarmingly inappropriate, as so vividly exemplified in the following from Berwick & Leape (1999; p136):

> *"Ladies and gentlemen, welcome aboard Sterling Airline's Flight Number 743, bound for Edinburgh. This is your captain speaking. Our flight time will be two hours, and I am pleased to report both that you have a 97% chance of reaching your destination without being significantly injured during the flight and that our chances of making a serious error during the flight, whether you are injured or not, is only 6.7%. Please fasten your seatbelts, and enjoy the flight. The weather in Edinburgh is sunny."*

As the authors point out, the safety statistics in airline travel are fortunately much better than the above, which were based on data for an adverse event (3.7% of hospital admissions) and serious preventable ADE (6.7% of hospital admissions) from the Harvard Medical Practice Study (Leape et al., 1991; Brennan et al., 1991); with 0.27 US airline fatalities per 1,000,000 flights between 1990 and 1994 (Berwick & Leape 1999). However, the source of the airline figures quoted was unclear. More recent data from the International Civil Aviation Organization (available from www2.icao.int/en/ism/iStars/Pages2/Accident statistics.aspx) reveal an accident rate of 4.2 per million departures and fatal accident rate 0.53 per million departures across the world in 2011. Nonetheless, the figures are still substantially smaller than those in health care.

An important point highlighted in the frequently quoted IOM's report is that there are a number of key differences between high-risk industries and health care (Kohn et al., 1999). First, front-line staff in high-risk industries are usually directly affected when an accident happens, while in health care, it is generally the third party, i.e. the patient, who is affected. Second, preventable harm in health care generally occurs to one patient at a time, rather groups of patients, thus making incidents less visible.

For MAEs, the problem of visibility also arises from the narrow window of opportunity for detecting the error before it reaches the patient (Leape et al., 1995; Bates et al., 1995), and the reported difficulties of detecting MAEs in practice (Barker & McConnell, 1962; Allan & Barker, 1990). Furthermore, if Reason's famous Swiss cheese model is considered, then a myriad of potentially 'invisible' latent conditions are also likely to have contributed to a patient incident. For example, findings from the study in chapter two revealed that 11.3% of doses due were not available from the patient's bedside medication locker or bedside area, thus causing an interruption to the drug round workflow and resulting in the nurse having to search for medications elsewhere. The reason for suggesting that this may be an 'invisible' latent condition is that while it may be reasonably expected that not all drugs would be available at the patient's bedside, the frequency of occurrence and subsequent delays to drug administration may have become accepted as part of routine practice and not 'seen' as a potential area for improvement. However, the findings from chapter two were based on observations on one ward only, and thus the generalisability of the findings is unknown.

Furthermore, findings from this thesis revealed that there was also no single standard for determining what constitutes an MAE (chapter three). This suggests some actions such as administering medications at the 'wrong time' are seen as errors by some researchers and not others, thus reducing the 'visibility' of MAEs. Although the example of definition variations reflect those that were used by researchers, there is also evidence that nurses

have different perceptions of what constitutes an MAE (Osborne et al., 1999). As part of the study by Osborne et al (1999), 57 nurses were asked to classify whether or not an error occurred in five scenarios. Overall, 35-91% of nurses classified the scenarios as a drug error (across the five scenarios), and depending on the scenario, 14-91% of nurses would complete an incident report form. This lack of consistency in what is considered an MAE together with difficulties of detection, and the presence of 'invisible' latent conditions are potentially important factors for why tackling MAEs in hospitals may be akin to the problem of "tackling the problem while blindfolded". These are also the reasons why the contributions of this thesis are likely to help health care professionals, policy makers, and researchers to 'see' the problem of MAEs more clearly, and therefore better able to develop interventions to reduce them. To better illustrate the potential implications of this research towards reducing MAEs, specific examples from this thesis are discussed in the next section in relation to two aspects: (1) development of proactive measures for systems improvement, and (2) contribution to system and process redesign.

7.3.2 Developing proactive measures to better 'see' potential areas for systems improvement

It has been suggested that approaches for identifying measures for improvement need to be both reactive and proactive (Carthey et al., 2001). Reactive measures provide important information about incidents that have occurred so that lessons may be learnt while proactive measures act as an early warning indicator of potential problems and latent conditions that may contribute to future incidents. Past research has generally focused on the reactive measures of safety by describing MAEs, analysing incident reports, and investigating the causes of MAEs (Hughes & Blegen 2008). However, findings from this thesis suggest that there are a number of ways in which proactive measures may be identified:

(1) **Examine non-conformity to typical local practices**. Findings from the MAPS study (chapter six) suggest that potential latent conditions for MAEs can be identified by examining non-conformity to local practices by nursing staff. With further work, the thematic framework conceptualised in the MAPS study (figure 6.2, chapter six) may be transformed into a checklist for identifying proactive measures for improvements; for example, by asking the user to consider the location and arrangement of human and material resources of the system under review.

(2) **Encourage feedback from ward staff and patients.** Ward staff and patients are a useful source of information for identifying actual and potential latent problems including sub-optimal structure-related aspects associated with the medication systems in use (chapters five and six). Enhancing feedback from everyday users of the systems is likely to yield more practical insights for improvement and has also been advocated by other research to increase safety in other parts of the medication process (Burnett et al., 2011). A strategy that was reported by a respondent of the national survey (chapter four) was the implementation of regular multidisciplinary walkarounds on inpatient wards. This not only provided an opportunity for staff to directly feedback any concerns in an informal and supportive manner, but also the systems and processes could be seen with a 'fresh pair of eyes' by those working outside of the ward and thus potentially better identify 'invisible' latent conditions (i.e. also addressed the suggestion in (1) above). Furthermore, this approach facilitated communication and discussions to create possible solutions for any problems that were identified, rather than let the problem continue and/or nurses having to persist with workarounds.

(3) **Measure and monitor variation associated with medication administration processes (use of statistical process control or 'SPC' methods).** Technically, this

method can be considered both reactive and proactive. It is reactive in that it involves measuring and monitoring events that have already happened, and proactive because it allows interpretation of the trends to predict whether or not variations were due to special causes (for example, to a specific new problem) or common causes (i.e. due to inherent variation within the system and process) (chapter one). The benefits of SPC is recognised within the NHS and much practical information is provided by the NHS Institute for Innovation and Improvement (Institute for Innovation and Improvement, 2013). However, specific measures of the medication administration process that could be monitored using SPC methods to identify potential problems were not provided. Based on the findings in this thesis, two potential measures are suggested: (i) duration of non-IV drug rounds and (ii) number of physical steps taken during non-IV drug rounds. Both of these can be easily measured (chapters two, five, and six), and may be sensitive to problems during the drug round, such as excessive interruptions and distractions (chapters five and six). The SPC approach would facilitate interpretation of what would otherwise be crude measures of quality by factoring in the inherent variations associated with drug administrations. Consequently, this method enables potential problems to be identified when the parameter being measured is over or under the expected limits of variation. The use of EPMA systems in the NHS provides an opportunity to potentially incorporate regular monitoring (either with SPC or generally) of other quality and safety measures that are less practical to do currently but are more directly relevant to MAEs: for example, timeliness of time-critical dose administrations and dose omissions (chapter two).

7.3.3 Understanding the context to better 'see' how systems and process may be redesigned to reduce MAEs

The problems of MAEs are substantial and previous research also suggests efforts to reduce errors should focus on systems and process improvement to redesign and 'mistake-proof' health care systems (Kohn et al., 1999; Grout, 2007). However, before systems and processes can be redesigned, it is necessary to consider the context in which they are to function.

Findings from the national survey, and medication storage and retrieval study (chapters four and five) revealed the extent to which inter- and intra-hospital similarities and variation exists in the systems and processes associated with medication administration. These provide information for those who are designing systems-based interventions that can be applied across the NHS. Additionally, findings from the MAPS study (chapter six), and the medication storage and retrieval study (chapter five), provide further insight into the variations in how existing systems were used in practice. For example, observations from the medication storage and retrieval study in chapter five suggest that the same types of medication storage may be implemented and used in different ways on different wards, and even within the same hospital. Consideration of design features to facilitate optimal implementation would therefore maximise the benefits of the system (or process) among all wards.

7.4 Future research

Throughout the course of this research, it has become apparent that increasing medication safety requires a multi-faceted approach, one which minimises latent error-producing conditions, strengthens and implements effective defence barriers, in addition to addressing

the causes of unsafe acts. Many of the findings from this thesis and other research in the area of patient safety has drawn on theories and techniques from a range of disciplines and carefully adapted principles from other complex and high-risk industries. Consequently a number of future research suggestions identified throughout this thesis also incorporate aspects of improving safety using these methods. Considering the overall findings and implications of this thesis, the additional research questions are as follows:

(1) How can non-conformity to local practices be better explored for their potential to detect error-producing conditions and/or behaviours that affect the safety of medication administration?

(2) How can ward-based medication storage systems be optimised to increase successful and efficient dose retrieval by staff and patients, and to facilitate accurate medicines reconciliation on admission and at discharge, while minimising wasted medicines?

(3) How can feedback from staff and patients be facilitated and incorporated into routine practice to increase medication safety?

(4) How useful are SPC charts for monitoring the quality and safety of drug administration and for detecting potential problems associated with the medication administration process?

(5) What other proactive measures of quality and safety should be monitored to facilitate continuous quality improvement of medication administration?

Based on the research, a key consideration would be involvement of individuals from a range of relevant disciplines and stakeholders in the medication administration process. These include (but not exclusively or definitively) human factors expert, psychologists, designers, ergonomists, nurses, doctors, pharmacy staff, and patients. The rationale is that each will bring a different perspective and thus together will provide a more comprehensive evaluation of the research. Furthermore, having multiple stakeholders means the research team is more likely to identify potential interactions between loosely coupled systems and

processes which may not necessarily be obvious to a pharmacist, a nurse, a doctor, or a patient alone.

7.5 Overall conclusions

Overall this thesis has extended the current knowledge of systems-based variation and their effects on the safety of medication administration. The extent of hospital medication systems in use across the NHS is now known which can be used to identify priority areas for developing systems-based interventions to reduce MAEs. Additional insight into the places in which nurses searched for medications during drug rounds has revealed the importance of considering the types of ward-based medication storage facilities available, and nurses' knowledge and assumptions regarding where different medications may be stored. While some differences in hospital medication systems between wards might be expected, the findings in this thesis suggest that potentially unnecessary system variations, such as how specific types of ward-stock are located on different wards, may benefit from a degree of standardisation to minimise the risk of MAEs. Furthermore, a detailed examination of how nurses worked within different hospital medication identified a number of actual and potential subtle systems-based effects on MAEs, medication administration workflow, interruptions, and distractions that have not been previously described. These had both positive and negative effects on the safety of medication administration and should be considered when developing and implementing systems-based interventions to reduce MAEs. Further research is required to explore methods for identifying how different hospital medication systems can be optimised to increase medication safety without compromising on efficiency, particularly in relation to ward-based medication storage systems.

In addition, this thesis has also extended the methodological knowledge on studying, interpreting, and reporting MAE rates. The research contributed to the area by summarising

methodological variations between MAE studies in the UK and quantifying their effects on reported MAE rates. This led to a set of methodological and reporting recommendations that can be applied to other countries. Further research is required to evaluate the recommendations, however it is anticipated that these would be useful for making future MAE studies more transparent and comparable.

An exciting challenge for future research is to explore methods for pro-actively monitoring the safety of the medication administration process, using comparable definitions and practical measures to act as an early warning indicator for potential error-producing conditions. The aim should be to develop a method for detecting potential medication safety-related problems as they arise and as health care evolves.

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Appendices

Appendix 1 – Drug round observation data collection form

A1	A2	A3	A4	B	C	
E1	E2	E3	E4	E5	E6	
F1	F2	F3	F4	F5	F6	
G	H	J	K1	K2	K3	K4

Page____ of _____

Medication administrations on scheduled drug rounds

Date:	Which drug round:	Observer:
Time started:	Time stopped:	Total no. of doses due for round:
Section of ward:	Census data:	Data entered in Excel:

Pt initials	Drug details	Bed	Time drug due	Dose observed by researcher?	Drug in locker?	ID check?	Admin Observed by nurse?	Error code	Signature code	Interviewed?	No. interruptions
EG	AUGMENTIN 625mg TDS PO	A1	2pm	✓	✓	✓	x	x	AN	x	III

Monsay McLeod 22nd May 2009
H:\PhD\Productive Ward. Medicines Module\Protocol and data collection form\Medication administration error record form.doc

Appendix 1 continued

Additional information for medical administration error data collection

Table 1. ERROR CODES

CODE	Type of MAE	Description
✖	No error	
OM	Omission	A dose of medication that has not been administered by the time of the next scheduled dose (does not include doses omitted according to doctor's instructions, nurse's clinical judgement, or if patient not on ward). See 'what do I have to record' for more guidance on this.
UO	Unordered drug	The administration of a drug that was not prescribed for the patient concerned (classified as a wrong drug error if drug X prescribed but drug Y given instead).
ED	*Extra dose*	The administration of an additional dose of a prescribed medication (includes administration of a drug more times in the day than prescribed and administration of a dose of drug after it has been crossed off the chart).
WM	*Wrong drug*	A dose of a drug administered that is not the drug prescribed (does not include generic substitution).
WR	*Wrong route*	The administration of the correct drug by a route or site that was not that prescribed.
WD	*Wrong dose*	The administration of the correct drug by the correct route but in a quantity that was not that prescribed (includes administration of incorrect number of dose units, selection of the wrong strength, and the measurement of an incorrect volume of an oral liquid). Where liquid preparations are not measured but instead poured into ungraduated medicines cups, a wrong dose error should be assumed to have occurred only when the observer is certain that the wrong volume has been administered. If failure to shake a bottle of suspension resulted in a visible concentration gradient this is also considered a wrong dose error.
WF	*Wrong pharmaceutical form*	The administration of the correct dose of the drug by the correct route but in a formulation that was not prescribed (includes administration of a modified release when non-modified prescribed, and vice versa). Does *not* include administration of enteric coated (EC) prednisolone instead of plain prednisolone tablets if patient states EC normally taken. Also, does *not* include appropriate purposeful alteration, such as substituting tablets with an equivalent soluble form or liquid to help administration.
DD	*Drug deteriorated*	Administration of a drug that has exceeded its expiry date or a drug with its physical or chemical integrity compromised.

Table 2. SIGNATURE CODES

CODE	Description
AS	Dose was administered and signed
AN	Dose administered but not signed
ND	Dose not administered and reason documented
NS	Dose not administered but signed to suggest it was administered
NN	Dose not administered and not signed (blank administration box)

Appendix 2 – Data extraction form for systematic review

Morwary McLeod

Data extraction form v5

Endnote ID: ..... Author/year:.....

Reviewer initials: ..... Date: ...../...../.....

Data entered by: .....

Date: ...../...../.....

Systematic review of Medication Administration Errors

DATA EXTRACTION

1. What was the study design?

a) **single centre** / **multi-centre** State centre(s) type: .....

.....

b) Descriptive: **survey**

Intervention: **cohort** (identify sample and identify control, then follow over time)

/**case-controlled** (i.e. identify sample and control, then look back into their history)

/ **controlled before & after**

/ **uncontrolled before & after**

Other: .....

c) For interventional studies, state type of intervention:

.....

.....

2. What population was studied?

a) **adult** / **paediatrics** / **both** / **age unclear**

b) state number and type of ward/specialty, and number of patients on each ward (if possible): .....

.....

.....

3. What method(s) for data collection was/were used?

a) **direct observation** / **chart review** / **incident reports** / **Other** (please state).....

b) For each method used, how many and who collected the data? .....

.....

c) Was any training provided? **Yes** / **No** / **Not stated** / **Some** (please state) .....

d) For each method used, when were data collected and for how long? .....

.....

.....

.....

.....

e) For studies which used direct observation, were the nursing staff told of the purpose of the study?

Yes / **No** / **Partial** (describe briefly) .....

f) For studies which used direct observation, did the observer(s) intervene to prevent errors identified?

Yes, all / **No** / **Yes, some** (describe briefly and state how many interventions made where possible)

.....

.....

4. What was the definition of a MAE used?

a) definition:.....

.....

.....

Appendix 2 continued

b) inclusion criteria:.....

.....

.....

c) exclusion criteria:.....

.....

.....

d) How many MAEs could be associated with one dose? .....

5. What was/were the denominator(s) and the definition used?

a) definition:.....

.....

.....

.....

.....

b) inclusion criteria:.....

.....

.....

c) exclusion criteria:.....

.....

.....

6. What were the results?

a) Sample size (number and denominator type): .....

.....

.....

b) Total number of MAEs and MAE rate identified (where applicable state name and number for each group type e.g. before and after. Also state numbers, rates and statistical significance values where reported): .....

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Appendix 2 continued

7. Were severity assessments conducted? **YES** (continue) / **NO** (skip to Q8.)
   a) How were MAEs assessed for severity? (state if validated tool used)
   .....
   .....
   .....
   b) What severity classification was used? .....
   .....
   .....
   c) What was severity based on? **Actual harm** / **potential harm** / **both** / **unclear**
   d) What was the proportion of MAEs in the two worst categories: (e.g. **severe** / **clinically significant**)
   Category.....No of MAE..... MAE rate of all MAEs.....
   Category.....No of MAE..... MAE rate of all MAEs.....
8. What were the causes of MAE identified (include data where presented). Skip to Q9 if no causes discussed
.....
.....
.....
.....
.....
.....
.....
.....
.....
9. Does the corresponding author need to be contacted to obtain further info? **Yes** / **No**
If so, write name and email address .....
Which questions need clarifying? .....

VALIDITY CONSIDERATIONS

1. Were the aims and or objectives of the study clearly stated? **YES** / **NO**
2. Was the study design appropriate to answer the research question? **YES** / **NO**
3. Did the research design allow equal opportunity for evidence that would prove and evidence that would disprove the hypotheses? (i.e. the study should be designed such that it does not favour a particular outcome) **YES** / **NO** / **NA**
4. Was the setting in which the study was conducted described? **YES** / **NO**
5. Was the risk of selection bias accounted for in the design of the study? (e.g. the patients or wards or nurses or drug charts should not be selected in such a way that it would favour a certain result) **YES (select YES if no selection bias was identified)** / **NO**
6. Was the data collection method described clearly? **YES** / **NO**
7. Was a pilot test of the data collection tool conducted and stated (or previous work done referenced)? **YES** / **NO**

Appendix 2 continued

Monsey McLeod
Data extraction form v5

8. Was calculation of sample size described? **YES / NO / NA** (If yes, insert .....)
9. Were the results presented clearly? **YES / NO**
10. Were any attrition (e.g. incomplete data or participants who did not give consent) clearly stated? **YES (select YES if there was no attrition) / NO**
11. Has attrition (if any) been accounted for in order minimize and or estimate its effect on the results? **YES (select YES if there was no attrition) / NO**
12. Were confounding factors stated? **YES / NO**
13. Were confounding factors accounted for? **YES / NO**
14. Were appropriate statistical analysis tests performed and described? **YES / NO**
15. Was the level of significance stated? **YES / NO**
16. Was any other risk of bias you identified accounted for by the authors? (e.g. by calculating kappa for assessing inter-rater reliability? By anonymising and mixing data from multiple wards/centres before review?) **YES (select YES if there was no risk of bias identified) / NO**
17. Were limitations of the study listed? **YES / NO**
18. In general, was the reporting of the study clear throughout? **YES / NO**
19. Is each conclusion justified, based on a logical progression from the specific problem addressed through to the hypotheses tested, the procedures used, and the data obtained? **YES / NO**

Additional comments: .....

.....

.....

.....

MEDICATION ERROR SPECIFIC QUALITY CRITERIA

1. Was an operational MAE definition stated? **YES / NO**
2. Were the MAE categories specified? **YES / NO**
3. Were operational MAE categories defined or their definitions referenced? **YES / NO**
4. Was/were denominators specified? **YES / NO**
5. Was/were operational denominator(s) clearly defined? **YES / NO**
6. Was the MAE rate calculation described clearly? **YES / NO**
7. Were the inclusion or exclusion of intravenous (or non-intravenous administrations) clearly stated? **YES / NO**
8. Were the type of patient population studied (i.e. paediatric or adult) clearly stated? **YES / NO**
9. Was direct observation method used? **YES / NO**

Total number of criteria satisfied (out of 9): .....

Additional comments: .....

.....

.....

.....

ADDITIONAL VALIDITY CONSIDERATIONS FOR STUDIES COMPARING GROUPS (if applicable) **/ NA**

Appendix 2 continued

1. Was each group treated the same? (same methods) **YES / NO**
2. Was there a power calculation? **YES / NO** State power: .....
3. Were comparison group(s) accounted for by statistical analysis e.g. for confounding factors? **YES / NO**

Additional comments: .....

.....

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.....

.....

.....

OTHER COMMENTS

1. Comment on the validity of the study (if not already mentioned, e.g. Is the study free of suggestion of selective outcome reporting? Were the results sufficiently precise and believable? (large enough study size, sufficient duration to make it credible?) Do the results of this study fit with other existing studies?)

.....

.....

.....

.....

a) What are the strengths of the study (if not already mentioned)

.....

.....

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.....

.....

b) What are the weaknesses of the study (if not already mentioned)

.....

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2. How generalisable are the results for other UK hospitals?

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Appendix 3 – Comparison of 110 strategies to increase postal questionnaire response rates, adapted from Edwards et al. (2009).

No.	Group 1	Group 2	Number of trials (number of participants)	Odds ratio	95% CI
1	Horizontal orientation of response options	Vertical orientation of response options	1 (400)	3.12	1.63-5.96
2	Teaser on the envelope	No teaser on the envelope	1 (190)	3.08	1.27-7.44
3	Included a veiled threat in follow-up letters	Did not include a veiled threat in follow-up letters	1 (671)	2.09	1.49-2.93
4	More interesting or high salient questionnaire	Less interesting or low salient questionnaire	3 (2,711)	2.00	1.32-3.04
5	Monetary incentive	No incentive	94 (160,004)	1.87	1.73-2.03
6	Special delivery service	Standard delivery service	15 (18,931)	1.76	1.43-2.18
7	Shorter questionnaire	Longer questionnaire	56 (60,119)	1.64	1.43-1.87
8	Monetary incentive	Non-monetary incentive	13 (26,484)	1.62	1.39-1.88
9	Illustration on cover of questionnaire largely in black	Illustration on cover of questionnaire largely in white	1 (320)	1.62	1.04-2.53
10	Incentive given with questionnaire	Incentive given on return of completed questionnaire	24 (27,569)	1.61	1.36-1.89
11	Mentioned obligation to respond	No mention of obligation to respond	3 (600)	1.61	1.16-2.22
12	Easiest questions first	Easiest questions were not first	2 (3,182)	1.61	1.14-2.26
13	SMS reminder	Postcard reminder	3 (9,947)	1.49	1.23-1.81
14	More user-friendly questionnaire	Less user-friendly questionnaire	1 (3,540)	1.46	1.21-1.75
15	Provided another copy of the questionnaire during postal follow up	Did not provide another copy of the questionnaire during postal follow up	11 (8,619)	1.46	1.13-1.90
16	Contacted participants before sending questionnaire	Did not contact participant before sending questionnaire	47 (79,651)	1.45	1.29-1.63
17	Multiple stamps on return envelopes	Single stamp on return envelopes	1 (510)	1.44	1.01-2.04
18	Follow-up contact	No follow-up contact	19 (32,778)	1.35	1.18-1.55
19	Factual questions	Factual and attitudinal questions	1 (1,280)	1.34	1.01-1.77

Appendix 3 continued

No.	Group 1	Group 2	Number of trials (number of participants)	Odds ratio	95% CI
20	Provided assurance of confidentiality	Did not provide assurance of confidentiality	1 (25,000)	1.33	1.24-1.42
21	University sponsorship	Non-university sponsorship	14 (21,628)	1.32	1.13-1.54
22	Large monetary incentive	Small monetary incentive	37 (84,043)	1.26	1.14-1.39
23	Hand-written address label	Computer-printed label	7 (5,091)	1.25	1.08-1.45
24	Stamped return envelope	Pre-paid business return envelope	27 (48,612)	1.24	1.14-1.35
25	Cover letters bearing a hand-written signature	Cover letters that had a scanned or typed signature	14 (15,006)	1.24	1.08-1.41
26	More relevant questions at the start of the questionnaire	More relevant questions were not placed at the start of the questionnaire	1 (5,817)	1.23	1.10-1.37
27	Single-sided questionnaire	Double-sided questionnaire	4 (4,966)	1.22	1.01-1.47
28	Non-monetary incentive	no incentive	94 (135,934)	1.15	1.08-1.22
29	Personal (e.g. signing letters by hand)	Not personal	58 (60,184)	1.14	1.07-1.22
30	Offered incentive first	Offered incentive in subsequent mailing	3 (7924)	1.14	1.02-1.28
31	First class postage	Non-first class postage	2 (8,300)	1.11	1.02-1.21
32	Endorsement by eminent professionals in the field	No endorsement by eminent professionals in the field	1 (395)	0.63	0.43-0.94
33	Double postcard	One page postcard	1 (600)	0.47	0.34-0.66
34	Asked participants not to remove an ID code	Did not ask participants not to remove an ID code	1 (100)	0.37	0.14-0.96
35	Priority stamps on return envelopes	First class stamp on return envelopes	1 (205)	0.26	0.14-0.46
36	Questionnaire sent one to five weeks after discharge from hospital	Questionnaire sent nine to fourteen weeks after discharge from hospital	2 (2,324)	2.26	0.69-7.37
37	Conventional mode of response technique	Randomised response technique	4 (7,345)	1.52	0.85-2.72
38	Sent from a GP	Sent from a research group	2 (1,106)	1.52	0.73-3.15
39	Questions ordered by time period	Questions not ordered by time period	1 (259)	1.48	0.84-2.59

Appendix 3 continued

No.	Group 1	Group 2	Number of trials (number of participants)	Odds ratio	95% CI
40	High frequency response alternatives	Medium frequency response alternatives	2 (3,882)	1.40	0.58-3.38
41	Signature within the questionnaire	No signature within the questionnaire	2 (1,030)	1.34	0.97-1.85
42	Included a consent form	Did not include a consent form	1 (414)	1.32	0.89-1.95
43	Telephone reminder	No reminder	3 (13,922)	1.29	0.85-1.96
44	Larger font	Smaller font	1 (650)	1.26	0.87-1.82
45	Open-ended questions first	Other types of questions first	1 (300)	1.26	0.73-2.19
46	Brown envelopes	White envelopes	5 (8,637)	1.23	0.81-1.87
47	Requested the participant's signature	Did not request the participant's signature	1 (201)	1.19	0.65-2.18
48	Pre-notification via telephone	Pre-notification via post	7 (3,322)	1.18	0.77-1.80
49	Coloured ink	Black or blue ink	3 (7,040)	1.16	0.95-1.42
50	Posting questionnaire to respondent's work address	Posting questionnaire to respondent's home address	2 (1,140)	1.16	0.89-1.52
51	Dot matrix printing	Letter-quality print	1 (176)	1.15	0.63-2.10
52	Requested an explanation for non-participation	No request for an explanation for non-participation	2 (1,907)	1.14	0.83-1.57
53	Asked participants to respond on the questionnaire itself	Asked participants to respond on a separate form	1 (200)	1.13	0.57-2.27
54	Identifying feature on questionnaire	No identifying-feature on questionnaire	8 (4,134)	1.12	0.82-1.52
55	Included a statement that others had responded	Did not include a statement that others had responded	1 (468)	1.12	0.76-1.65
56	Booklet	Stapled pages	3 (5,681)	1.10	0.99-1.23
57	Provided a time estimate for completion of the questionnaire	Did not provide a time estimate for completion of the questionnaire	1 (600)	1.10	0.76-1.58
58	Large non-monetary incentive	Small non-monetary incentive	7 (10,730)	1.09	0.97-1.22
59	Stressed how responses would benefit society	Did not stress how responses would benefit society	10 (12,731)	1.09	0.92-1.29

Appendix 3 continued

No.	Group 1	Group 2	Number of trials (number of participants)	Odds ratio	95% CI
60	Any sort of pre-paid return envelope	No pre-paid return envelope	4 (4,094)	1.09	0.71-1.68
61	Demographic questions first	Demographic questions were not first	4 (3,598)	1.08	0.94-1.25
62	Coloured letterhead	Black and white letterhead	1 (2,356)	1.08	0.91-1.28
63	Detailed cover letter	Brief cover letter	1 (500)	1.08	0.74-1.58
64	Ethnicity of the name of the person was identifiable	Ethnicity of the name of the person was not identifiable	5 (5,959)	1.07	0.9-1.27
65	Picture of researcher in the questionnaire	No picture of researcher in the questionnaire	4 (3,710)	1.07	0.76-1.53
66	Male investigator	Female investigator	2 (3,146)	1.07	0.72-1.58
67	Listing response options in increasing order	Not listing response options in increasing order	1 (6,783)	1.06	0.94-1.18
68	Included an appeal or a pleading factor in the cover letter	Did not include an appeal or pleading factor in the cover letter	2 (1,251)	1.06	0.79-1.42
69	Signed by a more senior or well-known person	Not signed by a more senior or well-known person	10 (5,644)	1.05	0.89-1.23
70	Printed on colour paper	Printed on white paper	14 (41,421)	1.04	0.99-1.10
71	Included 'don’t know' boxes	Did not include 'don't know' boxes	1 (1,360)	1.03	0.82-1.29
72	Told respondents that they would be contacted again if they did not respond	Did not tell respondents that they would be contacted again if they did not respond	7 (7,053)	1.02	0.91-1.15
73	Pre-contact by a medical researcher	Pre-contact by a non-medical researcher	2 (924)	1.01	0.55-1.86
74	Deadline to respond	No deadline to respond	6 (5,661)	1.00	0.84-1.19
75	Identifying number	Other identifier	1 (741)	1.00	0.68-1.46
76	Included a request for a telephone number	Did not include a request for a telephone number	1 (702)	1.00	0.65-1.54
77	Received on Monday	Received on Friday	1 (460)	1.00	0.64-1.56

Appendix 3 continued

No.	Group 1	Group 2	Number of trials (number of participants)	Odds ratio	95% CI
78	Cartoon in the questionnaire	No cartoon in the questionnaire	1 (280)	1.00	0.62-1.62
79	Stressed how responses would benefit the sponsor	Did not stress how responses would benefit the sponsor	8 (10,908)	0.99	0.86-1.13
80	Stressed how responses would benefit the participant	Did not stress how responses would benefit the participant	9 (13,175)	0.98	0.82-1.16
81	Follow-up interval less than 31 days	Follow-up interval 31-60 days	2 (1,608)	0.97	0.75-1.26
82	Circle answer	Tick box format	2 (1,125)	0.96	0.74-1.26
83	Questionnaire responses were anonymous	Questionnaire responses were identifiable	2 (2070)	0.96	0.66-1.39
84	Window envelope on questionnaire response	Non window envelope on questionnaire response	2 (11,781)	0.96	0.61-1.49
85	Stamps on out-going envelopes	Franked out-going envelopes	6 (13,964)	0.95	0.88-1.03
86	Most general questions at the start of the questionnaire	General questions were not placed at the start of the questionnaire	3 (11,435)	0.95	0.83-1.09
87	Included a 'sensitive' question	Did not include a 'sensitive' question	10 (21,393)	0.94	0.88-1.00
88	Optional internet response	No optional internet response	1 (4,213)	0.93	0.82-1.05
89	Larger out-going envelope	Standard out-going envelope	1 (1,200)	0.93	0.74-1.17
90	Closed questions first	Other types of questions first	1 (300)	0.93	0.54-1.59
91	Commemorative stamps on return envelopes	Standard stamps on return envelopes	5 (5,461)	0.92	0.81-1.06
92	Study logo on several items	Study logo on questionnaire only	1 (1,000)	0.92	0.72-1.18
93	Offered participants the choice to opt-out	Did not offer participants a choice to opt-out	4 (3,555)	0.92	0.66-1.28
94	First class stamp on return envelopes	Second class stamp on return envelopes	1 (800)	0.91	0.69-1.21
95	Multi-option consent form	Standard consent form	1 (200)	0.91	0.49-1.68
96	Offered survey results as incentive	No offering of survey results	12 (15,256)	0.90	0.76-1.07

Appendix 3 continued

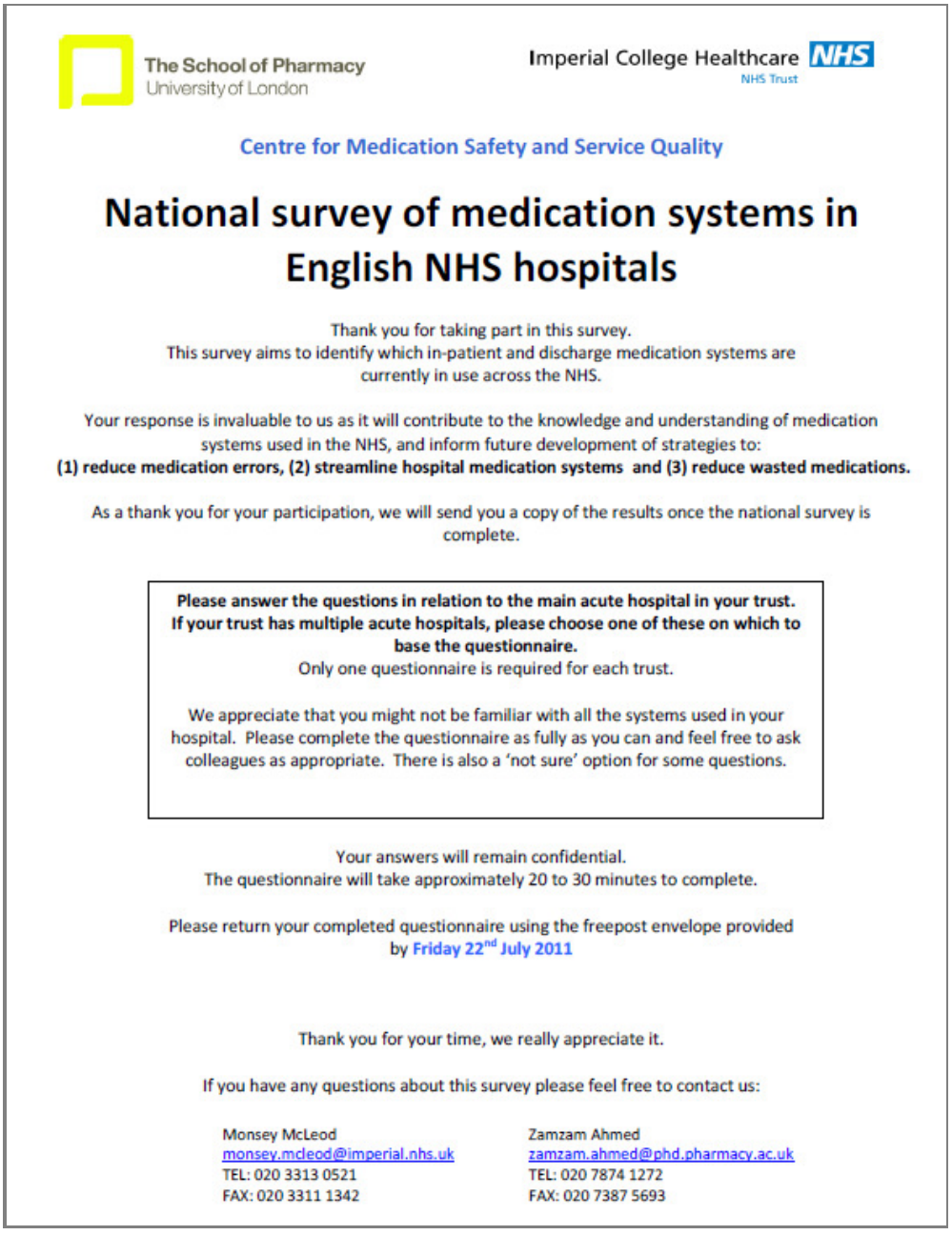
No.	Group 1	Group 2	Number of trials (number of participants)	Odds ratio	95% CI
97	Provided instructions for completion of the questionnaire	Did not provide instructions for completion of the questionnaire	1 (2,000)	0.89	0.74-1.06
98	Individual-item question format	Stem-and-leaf question format	1 (1,500)	0.88	0.70-1.10
99	University printed envelope	University not printed on the envelope	1 (500)	0.88	0.61-1.28
100	Large paper	Standard paper	2 (2,145)	0.88	0.56-1.39
101	Questionnaire sent with a supplement	Questionnaire sent alone	1 (1,795)	0.86	0.70-1.07
102	Telephone follow-up	Postal follow-up	5 (2,254)	0.86	0.54-1.36
103	Stamped addressed return envelopes	Addressed return envelopes (no stamp)	1 (147)	0.86	0.45-1.65
104	Mailed on Monday	Mailed on Friday	1 (504)	0.83	0.58-1.17
105	High quality or thicker paper	Standard paper	2 (1,039)	0.80	0.6-1.06
106	Check categories or specify numbers	Check categories only	1 (740)	0.80	0.60-1.06
107	5-step response scale	10-step response scale	1 (654)	0.78	0.52-1.19
108	Included responses for relatives	Did not include responses for relatives	2 (4,943)	0.67	0.60-0.76
109	Matrix form in questionnaire	Standard form in questionnaire	2 (316)	0.58	0.29-1.16
110	Open-ended question	Closed questions	3 (1,764)	0.31	0.09-1.04

GP, general practitioner; ID, Latin idem for identity; SMS, short message service

Appendix 4 – Comparison of postal versus on-line survey methods. *Costs were based on administering the questionnaire to 165 hospitals representing 165 NHS acute hospital trusts in England (at 2011 price values)

	Postal survey	Internet-based survey
Cost	**Approx. £197*** INCLUDES: ▪ Paper ▪ Printing ▪ Postage and envelopes ▪ Return stamped envelopes EXCLUDES: Cost of follow-up questionnaires	**Approx. £220*** INCLUDES: ▪ 12-month subscription for SurveyMonkey ▪ Telephone calls to obtain chief pharmacist email addresses
Time	Required for: ▪ Addressing and sending ▪ Postal transit ▪ Transcribing responses	Required for: ▪ Telephone calls ▪ Downloading responses
Addressing the respondent	▪ Send to "Chief Pharmacist" (list of 165 trusts and addresses available from NHS Choices)	▪ Requires an email address for link to questionnaire to be sent electronically ▪ Or post an invitation to participate in the study that includes the web-link to the internet survey
Ease of access to questionnaire	Advantages: ▪ Paper copies supplied Disadvantages: • Paper copies may get lost	Advantages: ▪ Hyperlink included in email Disadvantages: • Web-site of internet-based survey may be prohibited at some hospitals
Ease of completion	Advantages: ▪ Easy to read on paper ▪ No access to computer required ▪ No access to internet required ▪ Can be completed wherever Disadvantages: ▪ Questionnaire may seem long	Advantages: ▪ Link to questionnaire available ▪ Enables question filtering ▪ Optional mandatory fields ▪ Can go back and change answers Disadvantages: ▪ Requires computer access ▪ Requires access to internet
Information security	Risk of: ▪ Questionnaire being lost in the post or misplaced by respondents	Security ensured as: ▪ Information held on secure web-based software
Ease of questionnaire design	▪ Can design questions to any format	▪ 15 question templates available ▪ On-line guidance available
Ease of data management	▪ Requires transcription of returned questionnaires into a database	▪ 'Live' access to response data ▪ Responses are downloadable and avoids transcription

Appendix 5 – National survey of medication systems in English NHS hospitals questionnaire



The School of Pharmacy
University of London

Imperial College Healthcare NHS
NHS Trust

Centre for Medication Safety and Service Quality

National survey of medication systems in English NHS hospitals

Thank you for taking part in this survey.
This survey aims to identify which in-patient and discharge medication systems are currently in use across the NHS.

Your response is invaluable to us as it will contribute to the knowledge and understanding of medication systems used in the NHS, and inform future development of strategies to:
(1) reduce medication errors, (2) streamline hospital medication systems and (3) reduce wasted medications.

As a thank you for your participation, we will send you a copy of the results once the national survey is complete.

Please answer the questions in relation to the main acute hospital in your trust. If your trust has multiple acute hospitals, please choose one of these on which to base the questionnaire.
Only one questionnaire is required for each trust.

We appreciate that you might not be familiar with all the systems used in your hospital. Please complete the questionnaire as fully as you can and feel free to ask colleagues as appropriate. There is also a 'not sure' option for some questions.

Your answers will remain confidential.
The questionnaire will take approximately 20 to 30 minutes to complete.

Please return your completed questionnaire using the freepost envelope provided by **Friday 22nd July 2011**

Thank you for your time, we really appreciate it.

If you have any questions about this survey please feel free to contact us:

Monsey McLeod
monsey.mcleod@imperial.nhs.uk
TEL: 020 3313 0521
FAX: 020 3311 1342

Zamzam Ahmed
zamzam.ahmed@phd.pharmacy.ac.uk
TEL: 020 7874 1272
FAX: 020 7387 5693

Appendix 5 continued

PART ONE

This section is about the medication processes and resources currently in use at your hospital.

A: About your hospital

1. **What is the name of the trust that you work in?** _____

2. **How many acute hospitals are there in this trust?** _____acute hospitals

3. **What is the name of the hospital that you are answering this questionnaire for?** *Please answer the questions in relation to the main acute hospital in your trust. If your trust has multiple acute hospitals, please choose one of these on which to base the questionnaire.* _____

4. **What in-patient group(s) does this hospital treat?**
   - ☐ Adults only
   - ☐ Paediatrics only
   - ☐ Mixed adult and paediatrics

5. **Approximately how many in-patient wards are there in this hospital?** _____in-patient wards

B: Pharmacy service

For this section, please exclude any intensive care, maternity and/or mental health wards in your hospital. Please answer each statement in relation to what you see **in practice** on in-patient wards in this hospital, and not what could or should happen. **Please select one option for each part of the question, unless stated otherwise.**

6. **In general, a ward pharmacist visits the wards:**

a.	twice daily, every weekday on	☐ All wards *(skip to Question 7)* ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
b.	once daily, seven days a week on	☐ All wards *(skip to Question 7)* ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
c.	once daily, every weekday on	☐ All wards *(skip to Question 7)* ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
d.	two or three times a week on	☐ All wards *(skip to Question 7)* ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
e.	rarely or never on	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
f.	other (please specify):	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward

7. **Typically, how many hours a day is the pharmacy open in this hospital?** (for in-patient medication supply)
   - a. On weekdays _____hours/day
   - b. On Saturdays _____hours/day
   - c. On Sundays _____hours/day

8. **When the in-patient pharmacy is closed, which of the following are available?** *(Please select all that apply)*
   - a. ☐ On call pharmacist
   - b. ☐ Resident pharmacist
   - c. ☐ None of the above

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Appendix 5 continued

C: Medication supply and storage on in-patient wards.

For this section, please continue to exclude any intensive care, maternity and/or mental health wards in your hospital. Please answer each statement in relation to what you see **in practice** on in-patient wards in this hospital, and not what could or should happen. **Please select one option for each part of the question, unless stated otherwise.**

9. (i) In general, in-patient wards in this hospital use:

a.	patients' own supplies (medications from home) on	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
b.	ward stock on	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
c.	non-stock medications labelled for in-patient use (no directions on label) on	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
d.	one-stop dispensing supplies (directions on label for patient) on	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
e.	other (please specify): _____	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward

9.(ii) In your experience, which three types of medication supplies (*a to e above*) are most commonly used on in-patient wards in your hospital? *(please enter the relevant letter from above)*

Most common: _____

2nd most common: _____

3rd most common: _____

10. (i) In general, non-stock medications are ordered during pharmacy opening hours:

a.	via the ward pharmacist on their ward visit	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
b.	via the ward pharmacy technician on their ward visit	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
c.	by contacting the ward pharmacist outside of their ward visit	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
d.	by taking the drug chart to pharmacy	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
e.	by computer/ electronically	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
f.	other method(s) (please specify): _____	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward

10.(ii) In your experience, which three methods (*a to f above*) are most commonly used on in-patient wards in your hospital? *(please enter the relevant letter from above)*

Most common: _____

2nd most common: _____

3rd most common: _____

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Appendix 5 continued

11. (i) In your experience, which of the following methods are used to obtain medications for in-patient wards outside of pharmacy opening hours? *(Please select all that apply)*

a. ☐ Borrow from another patient's supply on the same ward (already labelled and supplied from hospital pharmacy)
b. ☐ Borrow from another ward (ward stock)
c. ☐ Contact the on-call pharmacist
d. ☐ Obtain the medication from a reserve/emergency drug cupboard (non-electronic)
e. ☐ Obtain the medication from reserve/emergency drug cupboard (electronic)
f. ☐ Other method(s) (please specify):

_____

11. (ii) In your experience, which three methods (*a to f above*) are most commonly used to obtain medications out of hours in this hospital?
(please enter the relevant letter from above)

Most common: _____

2nd most common: _____

3rd most common: _____

12. In general, oral medications are prescribed on:

(i) in-patient paper drug charts	(ii) in-patient electronic prescribing system
☐ All wards	☐ All wards
☐ Most wards	☐ Most wards
☐ Some wards	☐ Some wards
☐ One ward	☐ One ward
☐ No wards	☐ No wards
☐ Not sure	☐ Not sure

13. (i) In general, oral medications on the wards are stored in:

a. medicines cupboard	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure

13. (i) Continued. In general, oral medications on the wards are stored in:

b. shelves or units without doors	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
c. drug trolley (non-electronic)	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
d. electronic drug trolley	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
e. electronic storage cabinet (stationary)	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
f. fridge	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
g. controlled drugs cupboard (non-electronic)	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
h. controlled drugs cupboard (electronic)	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
i. patient's lockable bedside cabinet	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure

Question 13 continues on next page

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Appendix 5 continued

13. (i) Continued. In general, oral medications on the wards are stored in:

j.	patient's bedside table or belongings	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
k.	patient specific container located away from patient's bedside (e.g. in medication room)	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
l.	other location(s) (please specify): _____	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards

13. (ii) In your experience, where would oral medications most commonly be retrieved from *(a to l above)* at the time of administration in your hospital? *(please enter the relevant letter from above)*

Most common: _____

2nd most common: _____

3rd most common: _____

D: Medication administration, policies and guidance

For this section, please continue to exclude any intensive care, maternity and/or mental health wards in your hospital. Please answer each statement in relation to what you see **in practice** on in-patient wards in this hospital, and not what could or should happen. **Please select one option for each part of the question, unless stated otherwise.**

14. In general, regularly prescribed medications are administered on scheduled drug rounds on:

☐ All wards
☐ Most wards
☐ Some wards
☐ One ward
☐ No ward
☐ Not sure

15. For oral medications that are not stored at the patient's bedside, how are the medications transported to the patient from where they are stored?

a.	Lockable electronic drug trolley	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ Not available ☐ Not sure
b.	Lockable drug trolley (non-electronic)	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ Not available ☐ Not sure

15. Continued. For oral medications that are not stored at the patient's bedside, how are the medications transported to the patient from where they are stored?

c.	Trolley with no locks (non-electronic)	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ Not available ☐ Not sure
d.	Tray/basket	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ Not available ☐ Not sure
e.	Medicines cup/oral syringe	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ Not available ☐ Not sure
f.	Other (please specify): _____	☐ All wards ☐ Most wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure

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Appendix 5 continued

16. Excluding controlled drugs, which medications, if any, require a double check at administration in your hospital? *(i.e. administration is checked by a second member of staff)*

a.	Intravenous medications	☐ Yes ☐ No ☐ Not sure
b.	Intravenous fluids	☐ Yes ☐ No ☐ Not sure
c.	Oral chemotherapy	☐ Yes ☐ No ☐ Not sure
d.	Parenteral chemotherapy	☐ Yes ☐ No ☐ Not sure
e.	Doses administered to paediatric patients	☐ Yes ☐ No ☐ Not sure
f.	Specific drugs (e.g. heparin, insulin, please list) _____ _____ _____ _____	☐ Yes ☐ No ☐ Not sure

17. What medication administration related policies and guidance is there in your hospital?

a.	Self-administration of medications by in-patient	☐ Yes ☐ No ☐ Not sure
b.	Nil-by-mouth policy	☐ Yes ☐ No ☐ Not sure
c.	Intravenous administration guide (hard copy)	☐ Yes ☐ No ☐ Not sure
d.	Intravenous administration guide (electronic copy)	☐ Yes ☐ No ☐ Not sure
e.	Guidance on what to do if medication is not available on the ward	☐ Yes ☐ No ☐ Not sure
f.	Guidance on out of hours access to medications	☐ Yes ☐ No ☐ Not sure

18. Which of the following practices are routinely used on at least one ward in this hospital?

a.	Administration of medications by the patient's carer (e.g. parent, spouse)	☐ Yes ☐ No ☐ Not sure
b.	Nurses wear an overall/sash with "Do not disturb" or similar words during drug administration	☐ Yes ☐ No ☐ Not sure

Additional comments

19. Please tell us about any initiatives that have been implemented in your hospital to improve any of the following: pharmacy service to in-patients, medication supply and storage on in-patient wards and/or medication administration.
Please feel free to add any other comments you may have about the pharmacy service and/or medication processes in your hospital.

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Appendix 5 continued

PART TWO

This section is about current and/or planned electronic prescribing systems at your hospital.

E: Electronic prescribing systems

Thinking about all **in-patient and discharge** services in your hospital, please answer the following questions about electronic prescribing. **In this part, please also include any systems used on intensive care, maternity and mental health wards.**

Examples of electronic prescribing systems are:
- *Comprehensive hospital wide prescribing systems (e.g. JAC, Cerner)*
- *Speciality targeted applications/software (e.g. ChemoCare, Varian)*
- *Systems relating to a specific part of the prescribing process (Electronic discharge prescribing)*

20. Does your hospital have any electronic prescribing system in use at the moment?

Yes ☐ (continue to Question 21) No ☐ (skip to Question 30)

21. Is there more than one electronic prescribing system in use in your hospital at the moment?

Yes ☐ If Yes, please insert number of systems: _____
No ☐
Not sure ☐

22. Please insert the name of the electronic prescribing system(s) you have in the hospital.

Examples of electronic prescribing systems are:
- *Comprehensive hospital wide prescribing systems (e.g. JAC, Cerner)*
- *Speciality targeted applications/software (e.g. ChemoCare, Varian)*
- *Systems relating to a specific part of the prescribing process (Electronic discharge prescribing)*

System 1	System 2	System 3	System 4
_____	_____	_____	_____

23. How long has the system(s) been in place?	System 1	System 2	System 3	System 4
a. **<1 year**	☐	☐	☐	☐
b. **≥ 1 < 2 year**	☐	☐	☐	☐
c. **2 – 5 year**	☐	☐	☐	☐
d. **> 5 year**	☐	☐	☐	☐
e. **Not sure**	☐	☐	☐	☐

Please add any other comments you have about the questions on this page.

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Appendix 5 continued

24. Please answer all statements from (a to c) for each system you have in place.
The system you have allows:

	System 1	System 2	System 3	System 4
a. **Prescribing for in-patients**	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure
b. **Prescribing for discharge**	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure
c. **Others , please specify**	_____	_____	_____	_____

Please add any other comments you have. Insert the letter of the point you are referring to i.e. a. (comment) and name of system if necessary.

25. Please answer all statements from (a to h) for each system you have in place.
The system you have is in routine use in:

	System 1	System 2	System 3	System 4
a. **Adult intensive therapy units**	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
b. **Paediatric intensive therapy units**	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
c. **Adult medical wards**	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
d. **Adult surgical wards**	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
e. **Paediatric medical wards**	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure

Question 25 continues on next page

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Appendix 5 continued

25. Continued. Please answer all statements from (a to h) for each system you have in place.

The system you have is in routine use in:	System 1	System 2	System 3	System 4
f. **Paediatric surgical wards**	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
g. **Cancer services**	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure	☐ Not applicable ☐ All wards ☐ Some wards ☐ One ward ☐ No wards ☐ Not sure
h. **Others, please specify type of wards**	_____	_____	_____	_____

Please add any other comments you have. Insert the letter of the point you are referring to i.e. a. (comment) and name of system if necessary.

26. Which best describes your system for each statement? Please answer all statements from (a to f) for each system you have in place.

The system is:	System 1	System 2	System 3	System 4
a. **An in-house designed system** 'originally designed internally within the Trust'	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure
b. **Supplied by an external software supplier**	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure
c. **A stand alone application** 'operates without other programs'	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure
d. **Is linked with, or includes, the pharmacy dispensing software**	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure
e. **Is linked to other systems/ software in the hospital** *e.g. laboratory reports*	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure
f. **Is interfaced with other technologies** *e.g. bar-coding, electronic pumps.*	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure	☐ Yes ☐ No ☐ Not sure

Please add any other comments you have. Insert the letter of the point you are referring to i.e. a. (comment) and name of system if necessary.

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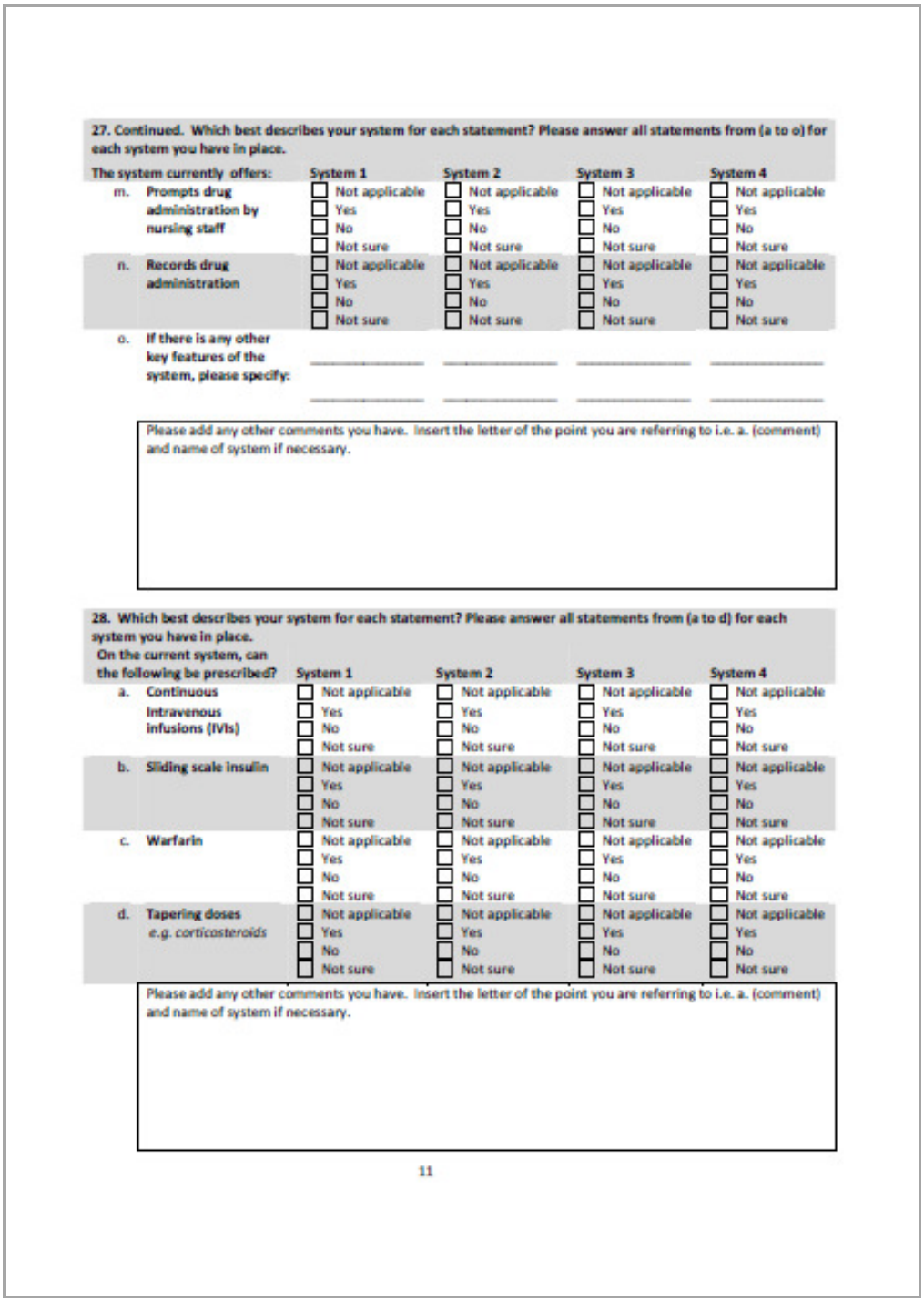
Appendix 5 continued

27. Which best describes your system for each statement? Please answer all statements from (a to o) for each system you have in place.

The system currently offers:	System 1	System 2	System 3	System 4
a. **Dose checking** 'checks that dose is within normal dose range'	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure
b. **Dose calculations** *e.g. calculates dose per weight, calculate infusion rate, etc.*	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure
c. **Free text prescribing option** 'i.e. typing drug name without selecting from a list of drugs'	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure
d. **Drug interaction alerts**	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure
e. **Multi level control for prescribers** 'different levels of authority tailored per prescriber'	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure
f. **Prescribing by selecting a drug from a drop down (or similar) menu**	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure
g. **Access to drug management information** *e.g. BNF, policies, guidelines, formulary*	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure
h. **Allergy checker** *e.g. electronic alert appears on screen*	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure
i. **Orders laboratory investigations**	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure
j. **Displays laboratory results**	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure
k. **Drug stock checking** 'checks if formulary drugs are available or out of stock'	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure
l. **Discharge/transfer summaries**	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure

Question 27 continues on next page

Appendix 5 continued



27. Continued. Which best describes your system for each statement? Please answer all statements from (a to o) for each system you have in place.

The system currently offers:	System 1	System 2	System 3	System 4
m. Prompts drug administration by nursing staff	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure
n. Records drug administration	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure
o. If there is any other key features of the system, please specify:	_____ _____	_____ _____	_____ _____	_____ _____

Please add any other comments you have. Insert the letter of the point you are referring to i.e. a. (comment) and name of system if necessary.

28. Which best describes your system for each statement? Please answer all statements from (a to d) for each system you have in place.

On the current system, can the following be prescribed?	System 1	System 2	System 3	System 4
a. Continuous Intravenous infusions (IVIs)	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure
b. Sliding scale insulin	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure
c. Warfarin	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure
d. Tapering doses *e.g. corticosteroids*	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure	☐ Not applicable ☐ Yes ☐ No ☐ Not sure

Please add any other comments you have. Insert the letter of the point you are referring to i.e. a. (comment) and name of system if necessary.

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Appendix 5 continued

29. Which drugs (if any) are prescribed on a supplementary paper drug chart? (Please select all that apply)

System 1	System 2	System 3	System 4
☐ None	☐ None	☐ None	☐ None
☐ Continuous IVIs	☐ Continuous IVIs	☐ Continuous IVIs	☐ Continuous IVIs
☐ Insulin	☐ Insulin	☐ Insulin	☐ Insulin
☐ Warfarin	☐ Warfarin	☐ Warfarin	☐ Warfarin
☐ Tapering doses	☐ Tapering doses	☐ Tapering doses	☐ Tapering doses
☐ Other (please specify)	☐ Other (please specify)	☐ Other (please specify)	☐ Other (please specify)
_____	_____	_____	_____

Please add any other comments you have. Insert the name of the system if necessary.

30. Does your hospital intend to introduce a new prescribing system(s)? If Yes, when:

☐ No ☐ <1 year ☐ 1-2 years ☐ >2 year ☐ Not sure

Please add any other comments you have.

31. Please provide your details below if you are happy for us to contact you in case any of your responses require further clarification. Your contact information will remain confidential.

Name: _____

Role/job title: _____

Email address: _____

Phone number: _____

Bleep number: _____

32. Thank you for completing this survey. The information you have provided will help us to identify what medication systems are currently in use and will contribute to the development of future strategies to (1) reduce medication errors, (2) streamline hospital medication systems and (3) reduce wasted medications. Would you be willing to be contacted for the next stage of our research?

☐ Yes ☐ No

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Appendix 6 – Pre-notification letter for national survey

The School of Pharmacy
University of London

Imperial College Healthcare NHS
NHS Trust

Centre for Medication Safety and Service Quality

Pharmacy Department
Charing Cross Hospital
Fulham Palace Road
London
W6 8RF

Chief Pharmacist,
Address
Address
Address

Date

Dear Chief Pharmacist,

National Survey of Medication Systems in English NHS hospitals

We are writing to let you know that within the next two weeks, you will receive a questionnaire and be invited to participate in a National Survey of Medication Systems in NHS hospitals conducted by the Centre for Medication Safety and Service Quality.

The survey aims to identify the types of systems, processes and resources currently used for prescribing, dispensing and administration of medication in hospitals nationwide. The findings will provide a better understanding of the variations that may exist and contribute to the development of strategies to

- reduce medication errors
- streamline hospital medication systems and
- reduce wasted medications.

We hope that you will be willing to participate.

A questionnaire will be posted to all the Chief Pharmacists at each acute NHS hospital trust in England. Your responses will provide invaluable information about your trust. We will send you a summary of the results once the study is complete, which we hope will be helpful to you locally; we will also publish in a peer reviewed journal.

In the meantime, please do not hesitate to contact us via monsey.mcleod@imperial.nhs.uk or telephone 0203 313 30521 if you would like any further information.

Many thanks for your time in advance.
Yours faithfully,

Professors Bryony Franklin and Nick Barber,
Monsey McLeod and Zamzam Ahmed (PhD students)
Centre for Medication Safety and Service Quality
A joint initiative between the Pharmacy Department, Imperial College Healthcare NHS Trust and The School of Pharmacy, University of London.

Appendix 7 – Cover letter mailed with the national survey

The School of Pharmacy
University of London

Imperial College Healthcare NHS
NHS Trust

Centre for Medication Safety and Service Quality

Pharmacy Department
Charing Cross Hospital
Fulham Palace Road
London
W6 8RF

Chief Pharmacist
Pharmacy Department
Norfolk and Norwich University Hospital
Colney Lane
Norwich
Norfolk
NR4 7UY

30th June 2011

Dear colleague,

We would like to invite you or a deputy to contribute to a national medication safety study that we are conducting across all acute NHS hospitals in England.

The study aims to identify the types of hospital medication systems, processes and resources currently being used for prescribing, dispensing and administration of medication in hospitals nationwide. This includes the use of electronic prescribing systems, the frequency of ward pharmacy visits, access to medications during and outside pharmacy opening hours and local strategies implemented to reduce medication errors.

The findings will help us to better understand the variations that may exist between NHS hospitals and subsequently contribute to the development of future strategies to:

- Reduce medication errors
- Streamline hospital medication systems
- Reduce wasted medications

The study has been approved by The School of Pharmacy's Research Ethics Committee.

What is involved?

Appendix 7 continued

We would be grateful if you (or a senior pharmacist) would complete the enclosed questionnaire for the main acute hospital in your trust. It will take approximately 20 to 30 minutes. If you have more than one main acute hospital in your trust, please choose one of these on which to base the questionnaire. Please return the completed questionnaire in the stamped addressed envelope provided by **Friday 22nd July 2011**.

What will I get from taking part?
We will provide you with a copy of the results once the study is complete which we hope will be useful for local service evaluation and development.

On behalf of the research team, I thank you for your time. If you have any questions about the study, please do not hesitate to contact us via monsey.mcleod@imperial.nhs.uk or telephone 0203 313 0521.

Yours faithfully,

Professors Bryony Dean Franklin and Nick Barber,
Monsey McLeod and Zamzam Ahmed (PhD students)

Centre for Medication Safety and Service Quality
A joint initiative between the Pharmacy Department, Imperial College Healthcare NHS Trust and The School of Pharmacy, University of London.

Appendix 8 – National survey follow-up letter to non-respondents

The School of Pharmacy
University of London

Imperial College Healthcare NHS
NHS Trust

Centre for Medication Safety and Service Quality

Pharmacy Department
Charing Cross Hospital
Fulham Palace Road
London
W6 8RF

Chief Pharmacist

4th August 2011

Dear colleague,

A few weeks ago, we sent you our "National survey of medication systems in English NHS hospitals" questionnaire, by post. If you have already completed and returned the questionnaire, please accept our sincere thanks for doing so – we will look forward to receiving your responses.

If you have not yet completed the questionnaire, we would be grateful if you or a deputy would do so at your earliest convenience. Your responses will help us to better understand the variations that may exist between NHS hospitals and subsequently contribute to the development of future strategies to:

- Reduce medication errors
- Streamline hospital medication systems
- Reduce wasted medications

If you did not receive the first questionnaire, please find one included with this letter, together with a FREEPOST return envelope.

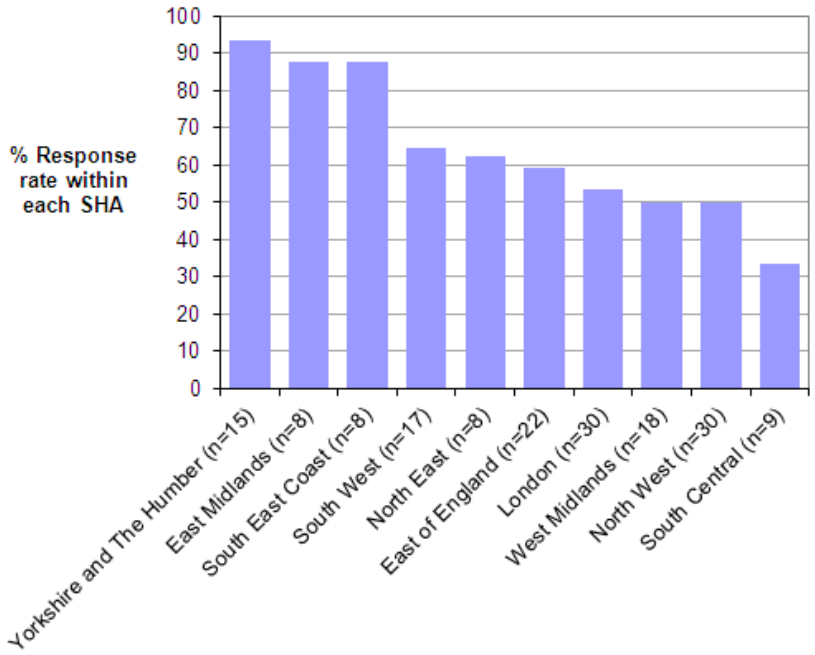
On behalf of the research team, we thank you for your time. Please feel free to contact us via monsey.mcleod@imperial.nhs.uk or telephone 0203 313 0521 if you have any questions about the survey.

Yours faithfully,

Professors Bryony Dean Franklin and Nick Barber,
Monsey McLeod and Zamzam Ahmed (PhD students)

Centre for Medication Safety and Service Quality
A joint initiative between the Pharmacy Department, Imperial College Healthcare NHS Trust and The School of Pharmacy, University of London.

Appendix 9 – Response rate within each of the then 10 strategic health authorities (SHA) in England. *n value represents the total number of acute and foundation National Health Service trusts in each SHA.*



Appendix 10 – Response rate for each question part in the national survey

Question	Number of responses (of total 100)	Question	Number of responses (of total 100)
1	100	12(i)	100
2	98*	12(ii)	100
3	100	13(i)a	92
4	100	13(i)b	88
5	89*	13(i)c	93
6a	96	13(i)d	91
6b	96	13(i)e	91
6c	96	13(i)f	95
6d	96	13(i)g	95
6e	96	13(i)h	91
6f (optional)	3	13(i)i	99
7a	100	13(i)j	89
7b	99	13(i)k	89
7c	98	13(i)l (optional)	0
8a	100	13(ii)	98
8b	100	14	99
8c	100	15a	100
9(i)a	95	15b	98
9(i)b	96	15c	80
9(i)c	97	15d	71
9(i)d	92	15e	72
9(i)e (optional)	3	15f (optional)	3
9(ii)	90	16a	97
10(i)a	95	16b	97
10(i)b	95	16c	97
10(i)c	91	16d	97
10(i)d	92	16e	97
10(i)e	91	16f	64
10(i)f (optional)	14	17a	99
10(ii)	94	17b	87
11(i)a	100	17c	97
11(i)b	100	17d	99
11(i)c	100	17e	98
11(i)d	100	17f	99
11(i)e	100	18(a)	89
11(i)f (optional)	10	18(b)	95
11(ii)	97	19 (optional)	32

**missing responses were amended using data retrieved from relevant trust websites*

Total number of respondents	100 (100%)
Total number of question parts	74
Number of question parts (excluding optional questions)	65
Median response rate per part (excluding optional questions)	97 (97%)
Min (excluding optional questions)	64 (64%)
Max (excluding optional questions)	100 (100%)

Appendix 11 – Drug trolley use in English NHS hospitals according to the then 10 Strategic Health Authorities

	Number of hospitals within the SHA that answered the question about use of drug trolleys	Number of hospitals that used drug trolleys on the majority of wards (%)
South Central	3	3 (100%)
South East Coast	7	6 (86%)
West Midlands	9	7 (78%)
London	16	11 (69%)
East of England	13	8 (62%)
South West	10	6 (60%)
Yorkshire and The Humber	12	7 (58%)
North East	5	2 (40%)
East Midlands	7	2 (29%)
North West	11	3 (27%)
Total	93	55 (59%)

Appendix 12 – Non one-stop dispensing (non-OSD) supplies used in English NHS hospitals according to the then 10 Strategic Health Authorities.

	Number of hospitals within the SHA that answered the question about use of non-OSD supplies	Number of hospitals that used non-OSD supplies on the majority of wards (%)
South Central	2	2 (100%)
East Midlands	7	6 (86%)
London	16	11 (69%)
North East	5	3 (60%)
South West	11	6 (55%)
South East Coast	7	3 (43%)
North West	10	4 (40%)
East of England	13	5 (38%)
Yorkshire and The Humber	12	4 (33%)
West Midlands	9	2 (22%)
Total	92	46 (22%)

Appendix 13 – Data collection form for the medication storage study

Codes for storage location

BL	Bedside locker	AW	Another ward	OL	Other locker
B	Bedside, not in locker	CD	CD cupboard in separate room	OT	Other trolley e.g. dressings trolley
DT	Drug trolley	F	Fridge in separate room	ODT	other drug trolley
SCB	Stock cupboard in bay	T	Nurse carries a 'tray' of meds on drug round	OBL	Other bedside locker
SCR	Stock cupboard in separate room			(O)PN	Other Pocket nurse

Medication storage study. *One form to be completed for each drug round observed.*

Date data entered:
Drug round ID:

Date:	**Drug round time: 8am / 12pm**	**Total number of beds on the ward:**
Observer:	**Ward:**	**How are drug rounds organised?**
Site: CXH / HH / SMH	**Section of ward observed:**	

Draw an overview of the ward layout and indicate where medications are stored on the ward.

Grade of nurse: Band 5 / 6 / 7 / other _____	**How many patients were given meds:**	**Pedometer steps:**
No of years qualified:	**Drug round start time:** hh : mm	**No. of patients observed on drug round:**
No of years experience on this ward:	**Drug round stop time:** hh : mm	**No. of patients due meds:**

Bed no	Drug chart missing?	Medication (write down drug name and dose of all doses due on this drug round, including nutritional supplements, intravenous and topical meds where observed)	Route	Storage locations accessed (see codes on top of page) and where retrieved from (circle it)?	Dose found on ward?	Dose given to patient?	Was the right drug prepared?	Comments (please use this space to document anything you think is relevant to the drug administration) **At the end of the drug round, ask the nurse:** (1) Would you consider that to be a typical drug round? ..... (2) How did you find being observed? ....
	Y/N				Y/N	Y/N	Y/N	
	Y/N				Y/N	Y/N	Y/N	
	Y/N				Y/N	Y/N	Y/N	

Page .....

Appendix 13 continued

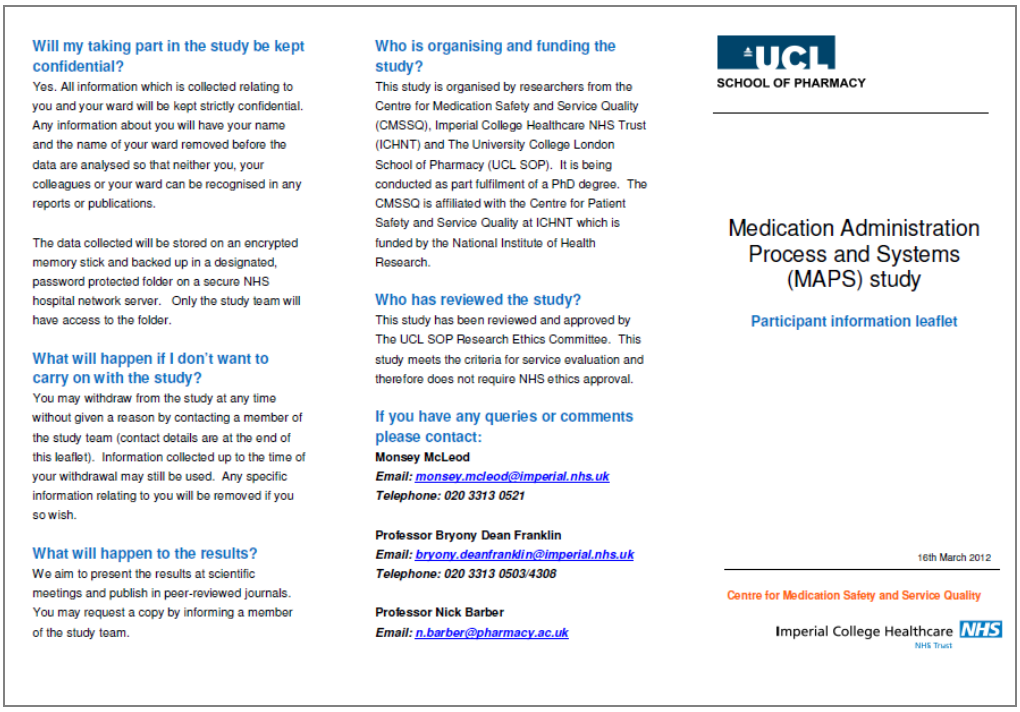
Codes for storage location

BL	Bedside locker	AW	Another ward	OL	Other locker
B	Bedside, not in locker	CD	CD cupboard in separate room	OT	Other trolley e.g. dressings trolley
DT	Drug trolley	F	Fridge in separate room	ODT	other drug trolley
SCB	Stock cupboard in bay	T	Nurse carries a 'tray' of meds on drug round	OBL	Other bedside locker
SCR	Stock cupboard in separate room			(O)PN	Other Pocket nurse

Bed no	Drug chart missing?	Medication (write down drug name and dose of all doses due on this drug round, including nutritional supplements, intravenous and topical meds where observed)	Route	Storage locations accessed (see codes on top of page) and where retrieved from (circle it)?	Dose found on ward?	Dose given to patient?	Was the right drug prepared?	Comments (please use this space to document anything you think is relevant to the drug administration) **At the end of the drug round, ask the nurse:** (1) Would you consider that to be a typical drug round? ..... (2) How did you find being observed? ....
	Y/N				Y/N	Y/N	Y/N	
	Y/N				Y/N	Y/N	Y/N	
	Y/N				Y/N	Y/N	Y/N	
	Y/N				Y/N	Y/N	Y/N	
	Y/N				Y/N	Y/N	Y/N	
	Y/N				Y/N	Y/N	Y/N	
	Y/N				Y/N	Y/N	Y/N	
	Y/N				Y/N	Y/N	Y/N	
	Y/N				Y/N	Y/N	Y/N	
	Y/N				Y/N	Y/N	Y/N	
	Y/N				Y/N	Y/N	Y/N	
	Y/N				Y/N	Y/N	Y/N	

Page .....

Appendix 14 – Participant information leaflet for the medication administration processes and systems (MAPS) study



Will my taking part in the study be kept confidential?

Yes. All information which is collected relating to you and your ward will be kept strictly confidential. Any information about you will have your name and the name of your ward removed before the data are analysed so that neither you, your colleagues or your ward can be recognised in any reports or publications.

The data collected will be stored on an encrypted memory stick and backed up in a designated, password protected folder on a secure NHS hospital network server. Only the study team will have access to the folder.

What will happen if I don't want to carry on with the study?

You may withdraw from the study at any time without given a reason by contacting a member of the study team (contact details are at the end of this leaflet). Information collected up to the time of your withdrawal may still be used. Any specific information relating to you will be removed if you so wish.

What will happen to the results?

We aim to present the results at scientific meetings and publish in peer-reviewed journals. You may request a copy by informing a member of the study team.

Who is organising and funding the study?

This study is organised by researchers from the Centre for Medication Safety and Service Quality (CMSSQ), Imperial College Healthcare NHS Trust (ICHNT) and The University College London School of Pharmacy (UCL SOP). It is being conducted as part fulfilment of a PhD degree. The CMSSQ is affiliated with the Centre for Patient Safety and Service Quality at ICHNT which is funded by the National Institute of Health Research.

Who has reviewed the study?

This study has been reviewed and approved by The UCL SOP Research Ethics Committee. This study meets the criteria for service evaluation and therefore does not require NHS ethics approval.

If you have any queries or comments please contact:

Monsey McLeod
Email: *monsey.mcleod@imperial.nhs.uk*
Telephone: 020 3313 0521

Professor Bryony Dean Franklin
Email: *bryony.deanfranklin@imperial.nhs.uk*
Telephone: 020 3313 0503/4308

Professor Nick Barber
Email: *n.barber@pharmacy.ac.uk*

UCL
SCHOOL OF PHARMACY

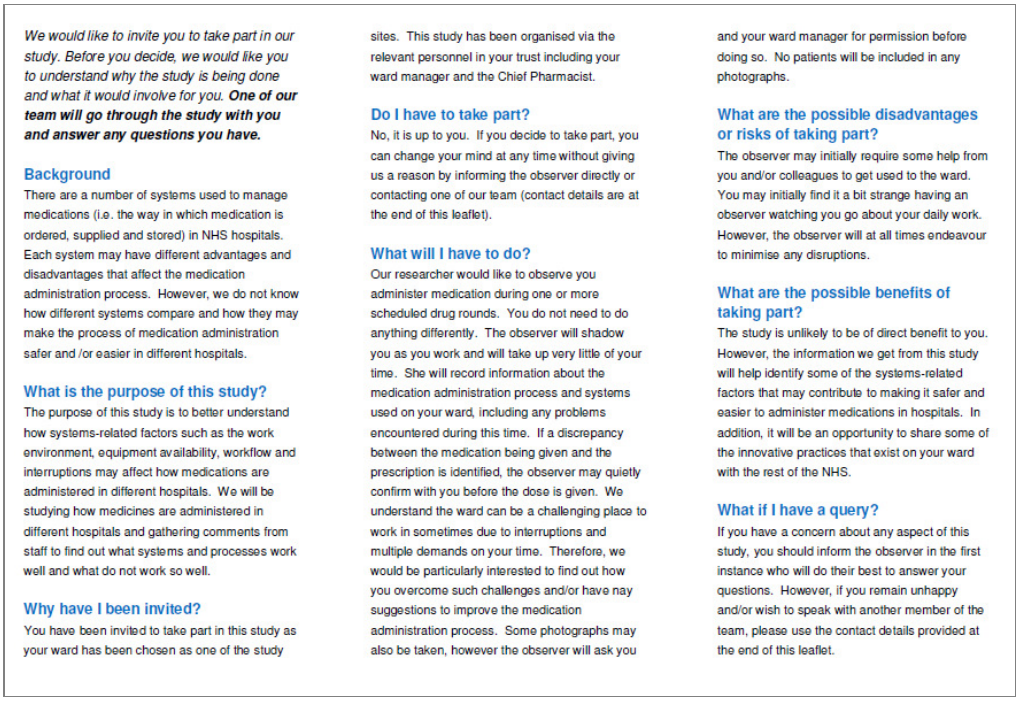
Medication Administration Process and Systems (MAPS) study

Participant information leaflet

16th March 2012

Centre for Medication Safety and Service Quality

Imperial College Healthcare NHS
NHS Trust



We would like to invite you to take part in our study. Before you decide, we would like you to understand why the study is being done and what it would involve for you. ***One of our team will go through the study with you and answer any questions you have.***

Background

There are a number of systems used to manage medications (i.e. the way in which medication is ordered, supplied and stored) in NHS hospitals. Each system may have different advantages and disadvantages that affect the medication administration process. However, we do not know how different systems compare and how they may make the process of medication administration safer and /or easier in different hospitals.

What is the purpose of this study?

The purpose of this study is to better understand how systems-related factors such as the work environment, equipment availability, workflow and interruptions may affect how medications are administered in different hospitals. We will be studying how medicines are administered in different hospitals and gathering comments from staff to find out what systems and processes work well and what do not work so well.

Why have I been invited?

You have been invited to take part in this study as your ward has been chosen as one of the study sites. This study has been organised via the relevant personnel in your trust including your ward manager and the Chief Pharmacist.

Do I have to take part?

No, it is up to you. If you decide to take part, you can change your mind at any time without giving us a reason by informing the observer directly or contacting one of our team (contact details are at the end of this leaflet).

What will I have to do?

Our researcher would like to observe you administer medication during one or more scheduled drug rounds. You do not need to do anything differently. The observer will shadow you as you work and will take up very little of your time. She will record information about the medication administration process and systems used on your ward, including any problems encountered during this time. If a discrepancy between the medication being given and the prescription is identified, the observer may quietly confirm with you before the dose is given. We understand the ward can be a challenging place to work in sometimes due to interruptions and multiple demands on your time. Therefore, we would be particularly interested to find out how you overcome such challenges and/or have nay suggestions to improve the medication administration process. Some photographs may also be taken, however the observer will ask you and your ward manager for permission before doing so. No patients will be included in any photographs.

What are the possible disadvantages or risks of taking part?

The observer may initially require some help from you and/or colleagues to get used to the ward. You may initially find it a bit strange having an observer watching you go about your daily work. However, the observer will at all times endeavour to minimise any disruptions.

What are the possible benefits of taking part?

The study is unlikely to be of direct benefit to you. However, the information we get from this study will help identify some of the systems-related factors that may contribute to making it safer and easier to administer medications in hospitals. In addition, it will be an opportunity to share some of the innovative practices that exist on your ward with the rest of the NHS.

What if I have a query?

If you have a concern about any aspect of this study, you should inform the observer in the first instance who will do their best to answer your questions. However, if you remain unhappy and/or wish to speak with another member of the team, please use the contact details provided at the end of this leaflet.

Appendix 15 – Participant consent form for the medication administration processes and systems (MAPS) study

Imperial College Healthcare NHS
NHS Trust

Centre for Medication Safety and Service Quality
Pharmacy Department
Charing Cross Hospital
Fulham Palace Road
London
W6 8RF

P: 020 3313 0521
E: monsey.mcleod@imperial.nhs.uk

Study Site Number: _____

Participant Identification Number: _____

CONSENT FORM

Title of Study: A study of medication systems in NHS hospitals

Name of Researcher: Monsey McLeod

Please initial each box

1. I confirm that I have read and understood the information sheet dated 16th March 2012 for the above study. I have had the opportunity to consider the information and ask questions.	
2. I understand that my participation is voluntary and I am free to withdraw at any time without giving any reason, without my employment or legal rights being affected.	
3. I understand that data collected during the study will be looked at by individuals from the research team. I give permission for these individuals to access the data collected.	
4. I understand that I may withdraw from the study at any time during the data collection period and that the information collected up until the time of my withdrawal may still be used. I give permission for the information collected during this period to be used.	
5. I agree to take part in the above study.	

_____ _____ _____
Name of participant **Date** **Signature**

I confirm that I have explained the study to the participant and have answered their questions honestly and fully.

_____ _____ _____
Name of person taking consent **Date** **Signature**

When completed: original for research file site and one copy for participant.

Appendix 16 – Data collection form for part 1 observations (qualitative data) of the medication administration processes and systems (MAPS) study

MAPS form part 1

Date:	**Nurse code:**	**Scheduled drug round time:**	**Section of ward:**	**No. of doses given:**
Observer:	**Length of time qualified:**	**Time observation began:** :	**Time first chart picked up:** :	**Pedometer steps:**
Site code:	**Length of time in this hospital:**	**Time observation stopped :** :	**Time last routine task done:** :	**Date data entered:**
Drug round ID:	**Length of time in this ward:**	**No. of patients on drug round:**	**No. of patients given meds:**	

Site S01, DR____, N___ Duration ___ minutes, ____steps

Additional information

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MAPS form 1 site S01 v1.0
27th March 2012

Page .....

Document below:
- Medication administration related tasks carried out before, during and after scheduled drug rounds
- 'Workaround' actions taken by nursing staff to overcome an actual and/or prevent a potential medication administration related problem
- Reported advantages and disadvantages of the medication system and medication administration process
- Any other notable medication administration related practices

During	After

MAPS form 1 site S01 v1.0
27th March 2012

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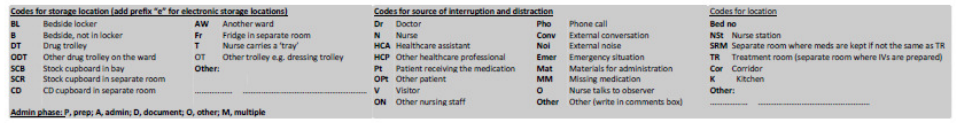
Appendix 17 – Data collection form for part 2 observations (quantitative data) of the medication administration processes and systems (MAPS) study



Codes for storage location (add prefix "e" for electronic storage locations)

BL	Bedside locker	AW	Another ward
B	Bedside, not in locker	Fr	Fridge in separate room
DT	Drug trolley	T	Nurse carries a 'tray'
ODT	Other drug trolley on the ward	OT	Other trolley e.g. dressing trolley
SCB	Stock cupboard in bay	Other:	
SCR	Stock cupboard in separate room		
CD	CD cupboard in separate room		

Admin phase: P, prep; A, admin; D, document; O, other; M, multiple

Codes for source of interruption and distraction

Dr	Doctor	Pho	Phone call
N	Nurse	Conv	External conversation
HCA	Healthcare assistant	Noi	External noise
HCP	Other healthcare professional	Emer	Emergency situation
Pt	Patient receiving the medication	Mat	Materials for administration
OPt	Other patient	MM	Missing medication
V	Visitor	O	Nurse talks to observer
ON	Other nursing staff	Other	Other (write in comments box)

Codes for location

Bed no	
NSt	Nurse station
SRM	Separate room where meds are kept if not the same as TR
TR	Treatment room (separate room where IVs are prepared)
Cor	Corridor
K	Kitchen
Other:	

MAPS form part 2

Date:	Nurse code:	Scheduled drug round time:	Section of ward:	Date data entered:
Observer: MM	Length of time qualified:	Time observation began: hh : mm	Age of pts:	Pedometer steps:
Site code:	Length of time in this hospital:	Time observation stopped: hh : mm	Time first chart picked up: hh : mm	No. patients nurse is looking after:
Drug round ID:	Length of time on this ward:	No. of patients on drug round:	Duration of drug round: hh : mm	
No. of staff on shift:			No. of patients given meds:	
Setting / general comments				

Bed no (and tick if chart at bedside)	Time dose due	Medication due (non-IV, only include IV dose if prepared and/or administered during drug round)	Route of admin Rx	Prep attempted	Storage locations accessed underline retrieved	P, POD OSD, S, stock I, inpatient	OE, prep, admin or not an OE	MAE
				Y/N			P/A/N	Y/N
				Y/N			P/A/N	Y/N
				Y/N			P/A/N	Y/N
				Y/N			P/A/N	Y/N

Lap no	I/D	I/D source	Admin phase P/A/D/ O/M	Location	Lap duration	Additional comments re actions taken and brief description of MAEs (if any) detected and locations searched for chart if not at bedside
	I/D				mm: ss	
	I/D				mm: ss	
	I/D				mm: ss	
	I/D				mm: ss	
	I/D				mm: ss	
	I/D				mm: ss	
	I/D				mm: ss	
	I/D				mm: ss	

MAPS form 2 v10.0
25 August 2012

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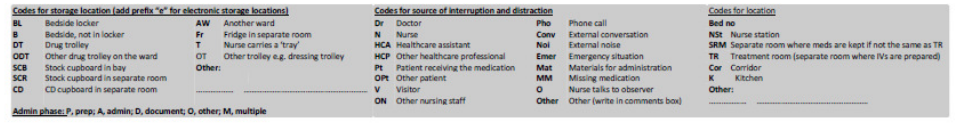

Codes for storage location (add prefix "e" for electronic storage locations)

BL	Bedside locker	AW	Another ward
B	Bedside, not in locker	Fr	Fridge in separate room
DT	Drug trolley	T	Nurse carries a 'tray'
ODT	Other drug trolley on the ward	OT	Other trolley e.g. dressing trolley
SCB	Stock cupboard in bay	Other:	
SCR	Stock cupboard in separate room		
CD	CD cupboard in separate room		

Admin phase: P, prep; A, admin; D, document; O, other; M, multiple

Codes for source of interruption and distraction

Dr	Doctor	Pho	Phone call
N	Nurse	Conv	External conversation
HCA	Healthcare assistant	Noi	External noise
HCP	Other healthcare professional	Emer	Emergency situation
Pt	Patient receiving the medication	Mat	Materials for administration
OPt	Other patient	MM	Missing medication
V	Visitor	O	Nurse talks to observer
ON	Other nursing staff	Other	Other (write in comments box)

Codes for location

Bed no	
NSt	Nurse station
SRM	Separate room where meds are kept if not the same as TR
TR	Treatment room (separate room where IVs are prepared)
Cor	Corridor
K	Kitchen
Other:	

Bed no (and tick if chart at bedside)	Time dose due	Medication due (non-IV, only include IV dose if prepared and/or administered during drug round)	Route of admin Rx	Prep attempted	Storage locations accessed underline retrieved	P, POD OSD, S, stock I, inpatient	OE, prep, admin or not an OE	MAE
				Y/N			P/A/N	Y/N
				Y/N			P/A/N	Y/N
				Y/N			P/A/N	Y/N
				Y/N			P/A/N	Y/N
				Y/N			P/A/N	Y/N
				Y/N			P/A/N	Y/N
				Y/N			P/A/N	Y/N
				Y/N			P/A/N	Y/N
				Y/N			P/A/N	Y/N
				Y/N			P/A/N	Y/N
				Y/N			P/A/N	Y/N
				Y/N			P/A/N	Y/N

Lap no	I/D	I/D source	Admin phase P/A/D/ O/M	Location	Lap duration	Additional comments re actions taken and brief description of MAEs (if any) detected and locations searched for chart if not at bedside
	I/D				mm: ss	
	I/D				mm: ss	
	I/D				mm: ss	
	I/D				mm: ss	
	I/D				mm: ss	
	I/D				mm: ss	
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MAPS form 2 v10.0
25 August 2012

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Appendix 18 – Sources externally-initiated interruptions and/or distractions described by Pape (2003) and definitions used in the medication administration processes and systems (MAPS) study. The sources have been additionally grouped into two main categories: 'individual' and 'technical' as described by Biron (2009).

Source	Definitions from Pape (2003)	Definitions used in MAPS study
Individual		
Physician	Physician or other medical provider distracts or interrupts the nurse administering medications	Physician **interrupts or observably distracts** the nurse **preparing,** administering, or documenting medications
Other personnel	Other personnel distract or interrupt the nurse administering medications	Not used.
Other patient	A different patient interrupts the nurse or the nurse must stop administering routine medications to attend to a different patient	A different patient interrupts **or observably distracts** the nurse **during preparation and/or administration task**
Visitor	A visitor or person other than an employee distracts the nurse administering medications	A visitor or person other than an employee **interrupts or observably** distracts the nurse **preparing and/or** administering medications
Other nurse	Not used	Another nurse interrupts or observably distracts the nurse preparing and/or administering medications
Health care assistant	Not used	A health care professional other than a doctor, nurse or health care assistant interrupts or observably distracts the nurse preparing and/or administering medications
Other health care professional	Not used	A health care professional other than a doctor, nurse or health care assistant interrupts or observably distracts the nurse preparing and/or administering medications
Patient	Not used	The patient interrupts or observably distracts the nurse during preparation and/or administration task
Technical		
Phone call	The nurse administering medications is interrupted by a phone call or places a phone call	The nurse **preparing and/or** administering medications is interrupted **or observably distracted** by a phone call
Missing medication	The nurse administering medications encounters one or more missing medications from the patient's drawer or the medication dispensing machine, which causes the nurse to take some action to retrieve the missing medication	The nurse encounters one or more missing medications from the **patient's bedside medication locker, bedside area, drug trolley, or alternative drug trolley container used on the drug round,** which causes the nurse to take some action to retrieve the missing medication **from a location in a**

Source	Definitions from Pape (2003)	Definitions used in MAPS study
		separate room to the patient (these are classified as an interruption and not as a distraction)
Wrong dose medication	The nurse administering medications encounters one or more wrong dose medications in the patient's drawer or the medication dispensing machine, which causes the nurse to take some action to retrieve the missing medication	Not used, these were included as 'missing medication'
Emergency situation	Any emergency situation such as a code or a patient's change in health that necessitates the nurse's immediate action	Any emergency situation such as a code or a patient's change in health that **the nurse has assessed as requiring immediate action (these are classified as an interruption and not as a distraction)**
External conversation	Loud conversation going on in the area, or any conversation not related to medication administration that the nurse engages in	Loud conversation going on in the area **that appear to distract the nurse or the nurse stops the preparation and/or administration task to engage in the conversation**
External noise	Loud noises audible to the nurse administering medications that appear to distract the nurse	Loud noises **that appear to distract the nurse or appear to cause the nurse to stop the preparation and/or administration task**
Materials for administration or clarification	Not used	The nurse identifies the need to obtain one or more materials for administration which causes he/she to take some action. It includes asking a colleague and/or contacting the prescriber for clarification of a medication order. (These are all classified as interruptions and not as distractions)
Other	Not used	Other sources of interruptions that could not be categorised into one of the ones listed above

Appendix 19 – Sources of self-initiated interruptions and/or distractions developed for use in the medication administration processes and systems (MAPS) study.

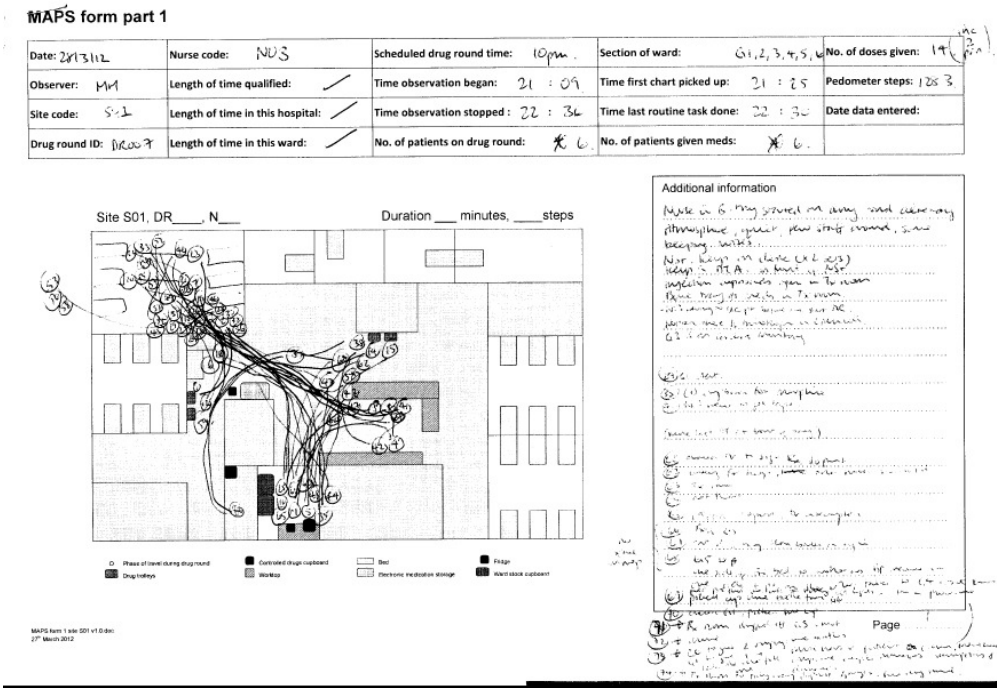
Sources	Definitions developed for use in MAPS study
Nurse	Nurse ceases the preparation and/or administration task without an observable external stimulus (these are classified as an interruption and not a distraction).
Observer	Nurse initiates interaction with the observer

Appendix 20 – Subcategories of medication administration errors (MAEs) used in the medication storage and retrieval study

MAE subcategory	Description by Allan and Barker (1990)	Definition used in the medication storage study (based on Franklin et al 2007 and findings from chapter three)
MAE at the preparation stage		
Unordered/ unauthorised drug	An unordered drug error occurs when a patient receives a medication for which the physician did not write an order. This includes those that result when a nurse switches medications for two patients; each patient is the victim of an unordered drug error (as well as an omission)	**Changed to "administration without a medication order"** based on findings from the systematic literature review in chapter three. MAEs should be classified as "administration without a medication order" if a drug is administered but was not prescribed at all for the patient concerned (classified as a wrong drug error if drug X prescribed but drug Y given instead).
Omission	An omission error takes place when a patient has not received his or her medication by the time the next dose is due.	**Included**. A dose of medication that has not been administered by the time of the next scheduled dose (does not include doses omitted according to doctor's instructions, nurse's clinical judgement, or if the patient was not on ward).
Wrong dose	A wrong dose error typically occurs when the patient receives an amount of medicine that is greater than or less than the amount ordered.	**Included**. The administration of the correct drug by the correct route but in a quantity that was not that prescribed
Wrong drug	Administration of the wrong drug was considered to an unordered drug error.	**Included**. A wrong drug error occurs when an incorrect drug is selected against an existing medication order (does not include generic substitution or therapeutic substitutions in accordance with trust policy).
Wrong dosage form	Wrong dosage form errors involve the administration of a drug in a dosage form different from the one that was ordered	**Included**. Administration of the correct dose of the drug by the correct route but in a formulation that was not prescribed (includes administration of modified release when non-modified prescribed, and vice versa). Does *not* include administration of enteric coated drug instead of plain tablets if the patient states enteric coated is normally taken, or any appropriate purposeful alteration, such as substituting tablets with a soluble equivalent to help administration.
Wrong time	A wrong time error occurs when the patient does not receive his or her medication within a predefined interval.	**Excluded**. Timing of drug administration in relation to the prescribed time was measured and reported but not included as an MAE.
Wrong dose preparation	Wrong dose preparation error occurs when a product is incorrectly manipulated before administration. Examples include not shaking an oral suspension.	**Excluded**. If wrong dose preparation such as failure to shake a bottle of suspension resulted in a visible concentration gradient this is was considered a wrong dose error.
Extra dose	An extra dose error occurs when the patient receives additional dosage units to those that were	**Included**. The administration of an additional dose of a prescribed medication (includes administration of a drug more times in the

	authorised, such as a dose administered after the order was cancelled.	day than prescribed and administration of a dose of drug after it has been crossed off the chart).
Drug deteriorated	A deteriorated drug error is reported when the physical or chemical integrity of a medication dosage form has been compromised, as with expired drugs or IV medications requiring refrigeration that are left out of the fridge.	**Included**. Administration of a drug that has exceeded its expiry date or a drug with its physical or chemical integrity compromised.
Other error at the preparation stage	When the investigator believes that a medication error has occurred but does not fall into a predefined subcategory	**Included**.
MAE at the administration stage		
Wrong patient	Not applicable	**New MAE subcategory** based on findings from the systematic literature review in chapter three. A wrong patient error occurs when the correct drug has been prepared for the correct medication order but administered to the wrong patient.
Wrong route	Wrong route errors occur when the correct form of drug is administered, but in the correct site on the patient's body.	**Included**. The administration of the correct drug by a route or site that was not that prescribed.
Wrong rate of administration	Wrong rate of administration errors can occur with infusions of intravenous fluids or liquid enteral products.	**Included**.
Wrong administration technique	Wrong administration technique errors involve using an inappropriate procedure during administration of a drug. Examples include wrong inhaler technique and not wiping an injection site with alcohol.	**Excluded**. Wrong administration technique errors such as wrong inhaler technique were considered a wrong dose, and not wiping an injection site with alcohol was considered a violation of procedure rather than an error.
Other error at the administration stage	When the investigator believes that a medication error has occurred but does not fall into a predefined subcategory	**Included**.
IV, intravenous; MAE, medication administration error		

Appendix 21 – An example of field notes recorded at site A for the medication administration processes and systems (MAPS) study



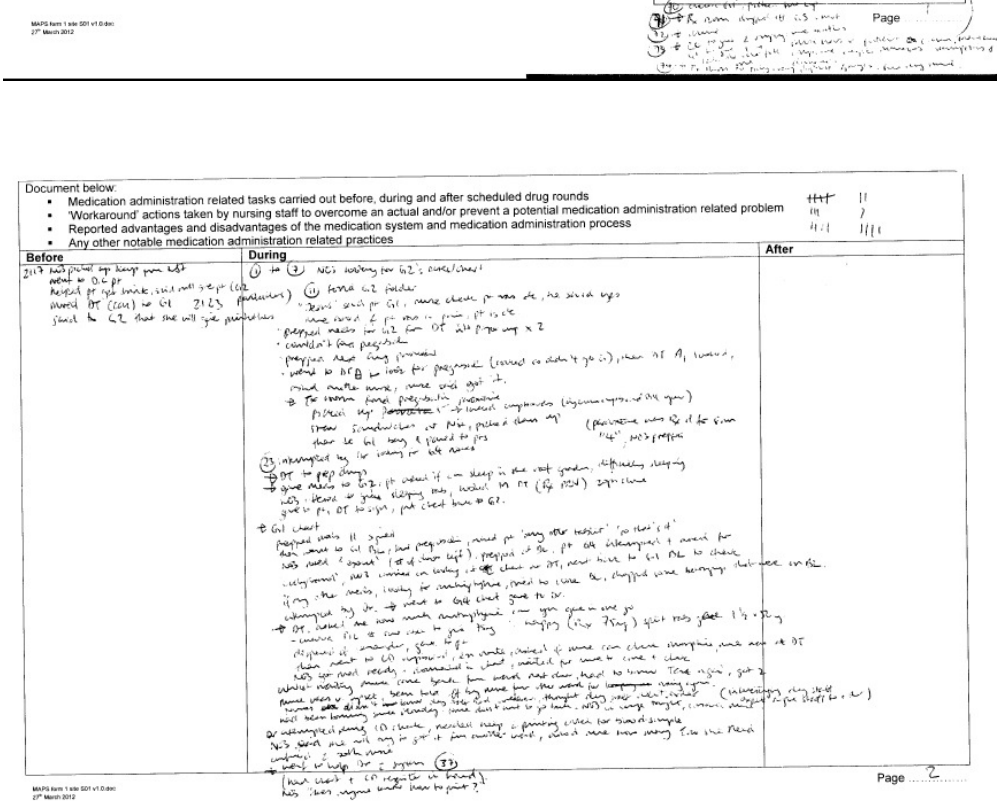
MAPS form part 1

Date: 28/3/12	Nurse code: NU3	Scheduled drug round time: 10pm	Section of ward: G1, 2, 3, 4, 5, 6	No. of doses given: 19
Observer: MM	Length of time qualified: ✓	Time observation began: 21 : 09	Time first chart picked up: 21 : 25	Pedometer steps: 1283
Site code: S01	Length of time in this hospital: ✓	Time observation stopped: 22 : 36	Time last routine task done: 22 : 30	Date data entered:
Drug round ID: DR007	Length of time in this ward: ✓	No. of patients on drug round: ~~6~~ 6	No. of patients given meds: ~~6~~ 6	

Site S01, DR___, N___ Duration ___ minutes, ____steps

Additional information

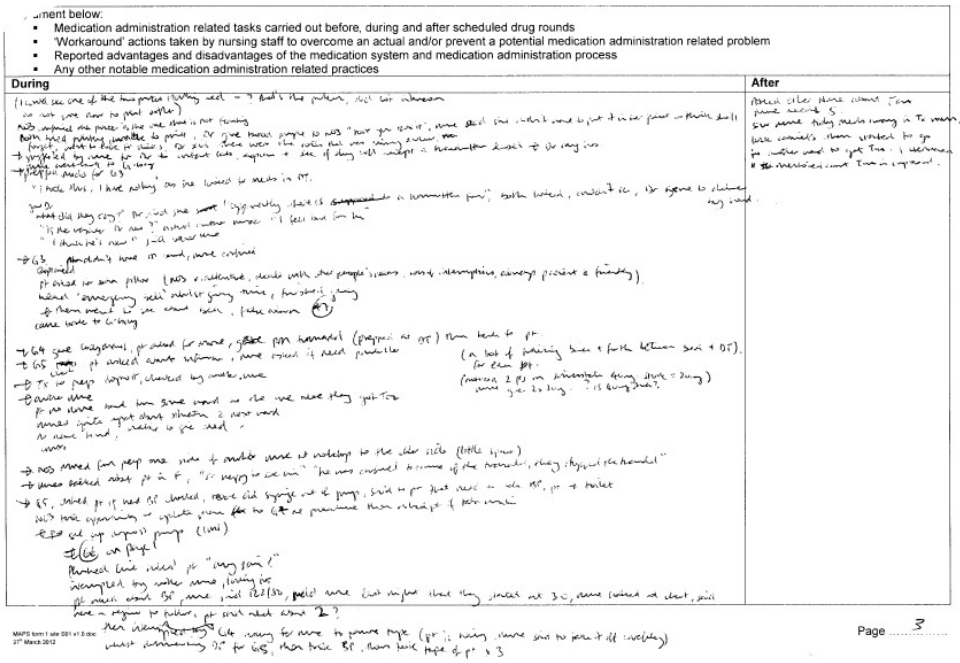
Page



Document below:
- Medication administration related tasks carried out before, during and after scheduled drug rounds
- 'Workaround' actions taken by nursing staff to overcome an actual and/or prevent a potential medication administration related problem
- Reported advantages and disadvantages of the medication system and medication administration process
- Any other notable medication administration related practices

Before	During	After

Page 2



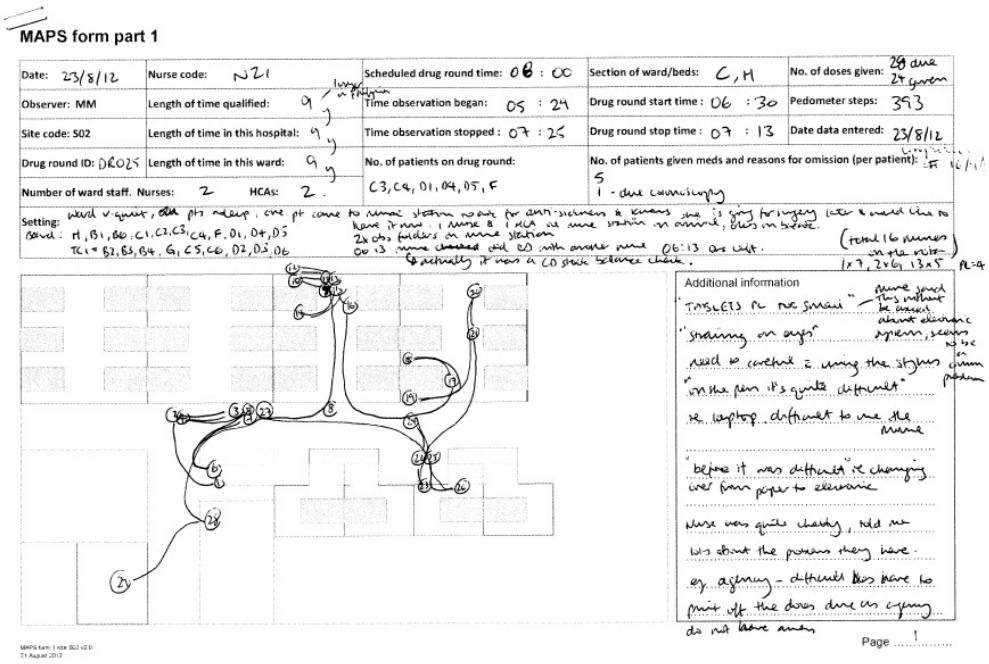
...ment below:
- Medication administration related tasks carried out before, during and after scheduled drug rounds
- 'Workaround' actions taken by nursing staff to overcome an actual and/or prevent a potential medication administration related problem
- Reported advantages and disadvantages of the medication system and medication administration process
- Any other notable medication administration related practices

During | After

Page 3

Appendix 22 – A sample of photographs taken at site A for the medication administration processes and systems (MAPS) study

Appendix 23 – An example of data collected at site B for the medication administration processes and systems (MAPS) study



MAPS form part 1

Date: 23/8/12	Nurse code: N21	Scheduled drug round time: 08 : 00	Section of ward/beds: C, M	No. of doses given: 29 due 27 given
Observer: MM	Length of time qualified: 9 y (long in pharm)	Time observation began: 05 : 29	Drug round start time: 06 : 30	Pedometer steps: 393
Site code: S02	Length of time in this hospital: 9 y	Time observation stopped: 07 : 25	Drug round stop time: 07 : 13	Date data entered: 23/8/12
Drug round ID: DR025	Length of time in this ward: 9 y	No. of patients on drug round: C3, C4, D1, D4, D5, F	No. of patients given meds and reasons for omission (per patient): 5 1 - dose commencing	
Number of ward staff. Nurses: 2 HCAs: 2				

Setting: ward v quiet, 6th pt asleep; one pt came to nurse station to ask for GTN - seemed to know where it was; 1 nurse & 1 HCA at nurse station on arrival, both on break.
Band: H, B1, B6, C1, C2, C3, C4, F, D1, D4, D5
TC1 = B2, B3, B4, G1, C5, C6, D2, D3, D6
2x obs huddled on nurse station
06:13 nurse ~~checked~~ did CD with another nurse 06:13 obs left.
(actually it was a CD stock balance check.

(total 16 nurses in pt's rooms 1x7, 2x6, 13x5) P1-4

Additional information
"TABLETS PC not SYRUP" — nurse joked they without be asked about allergies
"straining on eyes" — system seems to be a common problem
need to overlook & using the stylus
"on the pen it's quite difficult"
re laptop difficult to use the nurse
"before it was difficult re changing over from paper to electronic"
Nurse was quite chatty, told me lots about the problems they have - eg. agency - difficult they have to print off the doses due on agency do not have access

Page 1

MAPS form 1 site S02 v2.0
21 August 2012

Document below:
- Medication administration related tasks carried out before, during and after scheduled drug rounds
- 'Workaround' actions taken by nursing staff to overcome an actual and/or prevent a potential medication administration related problem
- Reported advantages and disadvantages of the medication system and medication administration process
- Any other notable medication administration related practices

Before

Patients re agency staff: print out not clear, compared to screen layout (nurse printed a copy for me)
All obs papers vs different doses in med times, need up
Need to enter doses given after on system as agency don't have access
Need to add IVs.

Used to paper
Get used to system
Nurse will not support to go home
Will need to get used to it
Easy once
Intravenous Administration
Intravenous Medication Profile
Unscheduled dose

Patients = pneumatic tubes
Cubicles = similar ward numbers
(same first name)
Medication sent to the wrong ward (referring to TTOs)
Nurse keep having to ask pharmacy
Pharmacy get frustrated, pt get frustrated

06:08 2 x obs arrived (main ~~elective~~ surgical)
~~Student~~ nurse went to meet them
(pair of med nurse joined us
shared equipment etc. pulling from same (arrived).

06:13 to 06:25 CD stock balance check

During

(nurse came out of store room & began (morning) medication + giving set)

(1) 06:30 NURSE START ON
(2) to give obs nurse (nurse was second checker)
(3) printed ~~off~~ "Patient PC" ~~nurse~~ on ~~trolley~~ PC, checked & MAR (should override C tray) if pt not on PC.
(4) & continued to talk to other nurse
(5) DT, put tray & ~~Medication~~ on DT (DT already had white tray & 2x paracetamol, 1 syringe, 1 insulin syringe?)
(6) Nurse started to pick up tray
(7) Back to DT, informed, ~~showed~~ (Patient PC was placed on ledge of DT)
(8) checked to C tray (paracetamol unable to log in to Patient PC)
(9) C3 spoke pt, but them what were being given
(10) to pt to give meds
(11) Went across on DT (from top) (instead of going to doorway)
(12) Went to pt to put up fluids, asked about allergies (NKDA).
(13) back to DT, disposed of sharp packaging & ~~set~~ set & syringe in tray on DT
(14) went around to the other side to retrieve used giving set
(15) back to DT, signed admin
(16) C4 good morning
"do you want some injection?" Pt asked why painkillers were withheld
Handover between pt, HCA & nurse
(noticed)
(17) D1 pt said joined a standard nurse for helping her last night
(18) Nurse checked obj
(19) Nurse went to pod other straight away
Pt continued to talk to nurse whilst she prepared meds
went to bedside locker & Patient PC

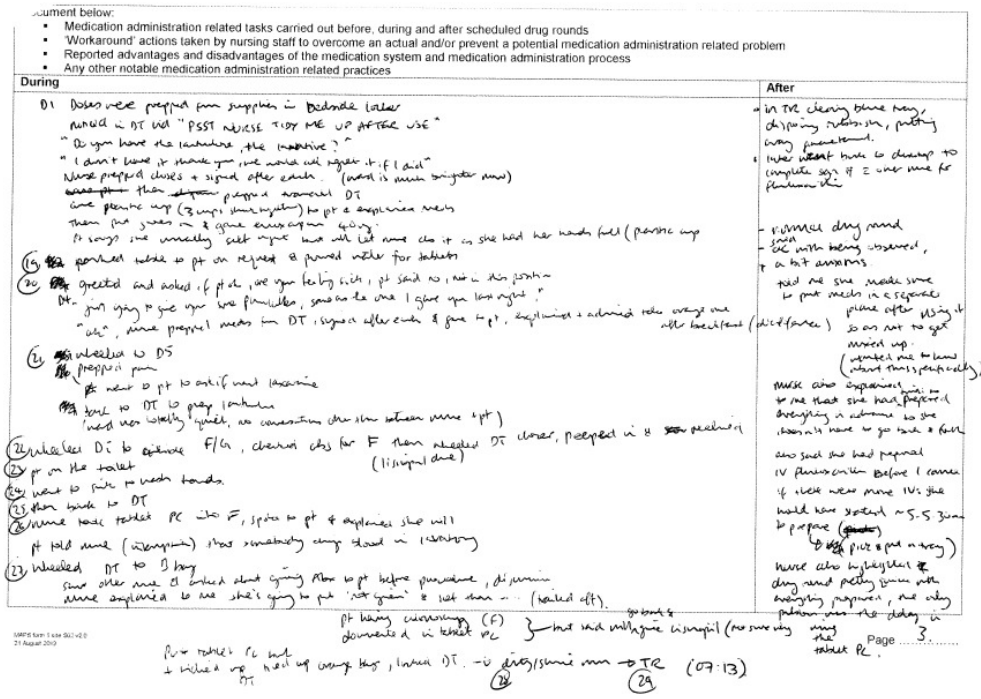
After

nurse explained re morphine
CD30 not given as spare at 23:00, need to sign out, By 9/24 : not done yet may done needed to have this changed by staff

Page 2

MAPS form 1 site S02 v2.0
21 August 2012

Appendix 23 continued



Document below:
- Medication administration related tasks carried out before, during and after scheduled drug rounds
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During

D1 Doses were prepared from supplies in Bedside Locker
Noticed in DT red "PSST NURSE TIDY ME UP AFTER USE"
"Do you have the medicine, the medicine?"
"I don't know if anyone you've worked out signed it, if I did"
Nurse prepared drugs + signed after each. (record is much brighter now)
~~was given~~ then ~~signed~~ prepared removed DT
one person cup (3 cups, some together) for pt & anaesthesia meds
then find yours in & give encouragement going.
pt says she usually sees right hand still but noted she is she had her meds fed (parkinsons cup
(15) ~~Re~~ provided tablet to pt on request & poured water for tablets
(20) ~~Re~~ greeted and asked if pt ok, how you feeling with, pt said no, not in this position
DT- just going to give you some painkillers, same as the ones I gave you last night."
"okay", nurse prepared meds from DT, signed after each & gave to pt, encouraged + administered tablets orange one after breakfast (did different)
(21) ~~Re~~ wheelied to DS
~~Re~~ prepared pain
~~Re~~ went to pt to ascertain next intervention
~~Re~~ went to DT to grasp conclusion
(need more totality/speech, see conversation other side between nurse + pt)
(22) wheelied DS to ~~Re~~ ~~Re~~ F/G, observed obs for F then accepted DT closer, accepted in ~~Re~~ ~~Re~~ ~~Re~~ (1) original dose
(24) pt on the toilet
(24) went to give to wash hands.
(25) then back to DT
(26) nurse took tablet PC into F, spoke to pt & explained she will
pt told nurse (interpreter) that sometimes clamp stood in intestine)
(27) wheelied DT to D bay
some other nurse at behind about giving Alan to pt before procedure, discussion
nurse explained to me she's going to put 'not given' & not given - (healed off).

pt having colonoscopy (F) } went with Morgan to hospital (no one else) using the tablet PC.
documented in tablet PC

Page 3

Pt re tablet PC not
I talked up DT
I talked up wrong drugs, talked DT. - U given/some given → TR (07:13)
(28) (29)

MAPS form 1 side SG2 v2.0
31 August 2010

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During

C3 0800 Tramadol PO/IM/IV "PO"
0800 Clotapamine PO
0800 Diclofenac PO
0800 Ranitidine PO
0800 Phenoxymethylpenicillin
C4 0642 Ibuprofen 400mg (PRN)
0900 Ant. / antacid given
D1 0800 Morphine prepared Step 3/2 rota — unsigned
(see nurse explanation)
0800 Amlodipine
0800 Furosemide
0800 Lansoprazole
0800 Lorazepam
0800 Mirtazapine
0800 Lactulose - "not given" PT refused med"
0800 Enoxaparin
0800 Paracetamol PO/IV - "given PO"
0800 Tramadol
0800 Cyanocobalamin
0800 ~~Re~~ Thiamine
0800 Metformin
D4 0800 Paracetamol PO/IV "given PO"
0800 Diclofenac
0800 Tramadol - "PO"
0800 Ant-convulsant
D5 0800 Diclofenac
0800 Lactulose
0800 Ferrous Sulphate
0800 Paracetamol PO/IV - "given PO"
F 0800 Lansoprazole ✓ given
0800 Paracetamol - not given
0800 Ranitidine ~~Re~~ ~~Re~~ ~~Re~~

Appendix 23 continued

```
**********      Active medication profile printed:  23Aug2012 at 05:45 *******

PATIENT NAME: [redacted]
Hosp No [redacted]          NHS No: [redacted]    Ref No [redacted]

Rx:      14
  AMLODIPINE 5MG TABLET                5 mg Oral OM
    START: 18Aug2012 0800
    PRESCRIBER: [redacted]
Next dose due:23Aug2012 at 0800

Rx:      15
  CINACALCET 30MG TABLET               30 mg Oral OM
with or after food
    START: 18Aug2012 0800
    PRESCRIBER: [redacted]
Next dose due:22Aug2012 at 0800

Rx:      16
  FUROSEMIDE * 40MG TABLET             40 mg Oral BD 8,12h
    START: 17Aug2012 1200
    PRESCRIBER: [redacted]
Next dose due:23Aug2012 at 0800

Rx:      17
  LOSARTAN 100MG TABLET                100 mg Oral OM
    START: 18Aug2012 0800
    PRESCRIBER: [redacted]
Next dose due:23Aug2012 at 0800

Rx:      20
  SIMVASTATIN 20MG TABLET              20 mg Oral ON
    START: 17Aug2012 2200
    PRESCRIBER: [redacted]
Next dose due:23Aug2012 at 2200

Rx:      22
  MOXONIDINE 200MCG TABLET             200 microgram Oral BD 8,20h
    START: 17Aug2012 2000
    PRESCRIBER: [redacted]
Next dose due:23Aug2012 at 0800

Rx:      96
  LACTULOSE ORAL LIQUID                10 mL Oral BD
REGULARLY WHEN REQUIRED FOR CONSTIPATIONReview after 2 days.
    START: 17Aug2012 1800
    PRESCRIBER: [redacted]                                    (WARD STOCK)
Next dose due:23Aug2012 at 0800

Rx:     106
  ENOXAPARIN 40MG/0.4ML SYRINGE        40 mg SC OM
    START: 17Aug2012 0800
    PRESCRIBER: [redacted]                                    (WARD STOCK)
Next dose due:23Aug2012 at 0800
```

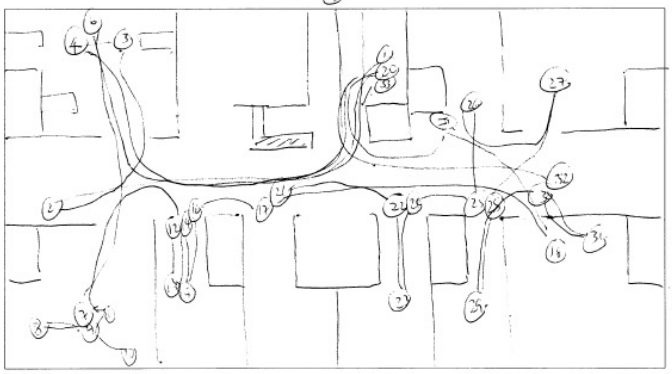
Appendix 24 – A sample of photographs taken at site B for the medication administration processes and systems (MAPS) study

Appendix 25 – An example of data collected at site C for the medication administration processes and systems (MAPS) study

MAPS form part 1

Date: 14/11/12.	Nurse code: N33 + N84	Scheduled drug round time: 12 : 00.	Section of ward/beds: CHTB.	Date data entered:
Observer: MM	Length of time qualified: 1½y	Time observation began: 12 : 07	Age of pts:	Pedometer steps: 513. 813 including 3 spins
Site code: S03	Length of time in this hospital: 4y.	Time observation stopped: 13 : 00	Drug round start time: 12 : 07	No. of doses due: 13
Drug round ID: DRC 44	Length of time in this ward: 1½ y.	No. of patients on drug round: 7 + 2 PEG supplies	Drug round stop time: 12 : 31	No. of doses given: 12
Number of ward staff. Nurses: 2	HCAs: 4	No. of patients given meds: 7 + 2 PEG supplies	Typical drug round?	Improve obs? X

Setting: Arrived 11:40 HCA at NS, NURSE in MDT Meeting?? 4 Pt Rides at NS?. 19 pts on ward - Found 1 alone in treatment room (had order in in NSS incoming comment) Start med typ from doctor (



Additional information

(2) to release COW
(3) to day —
(6) Left COW + tray in prepare of from 4 to chest IV in obs
(10) to retrieve obs reference
(20) to get more IVI (Finding)

Document below

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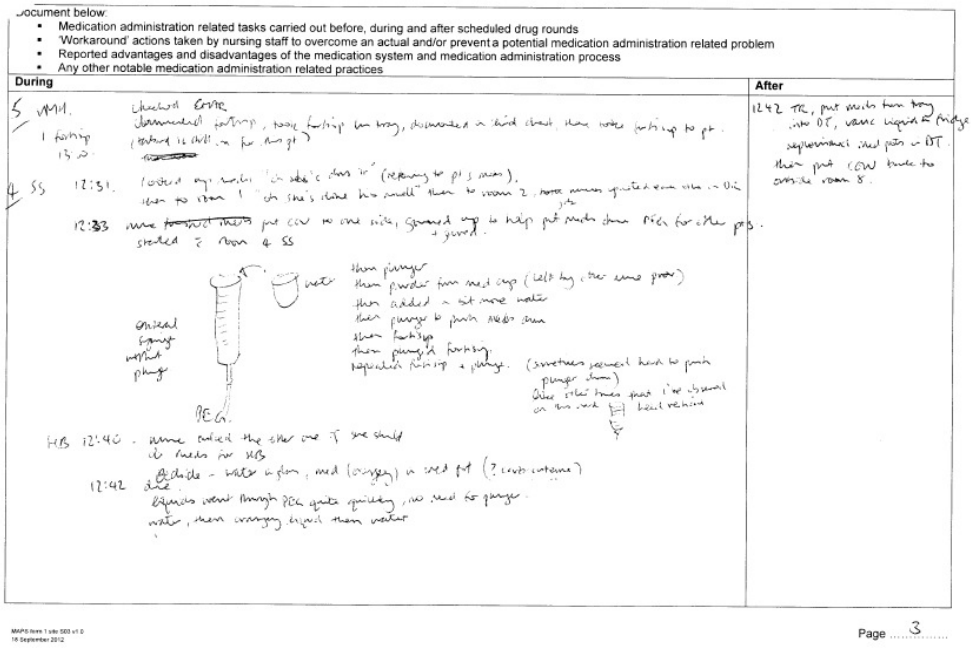
Before	During	After
12 07 Opened DC in TR) trolley up meal pms Drew up thin, nurse told me they are going to ignore DR, come on exam 5.2nd. Blue tray 2 to cupboard 625 Ranitidine 150 Paracetamol brown Fe/Folic Multi-vit plastic syr. ~~Blood~~ take blue tray as planned in COW cupboard when ↓.	Room 12:08 LM checked x-ceen to BL Refused meds (1 opt nur req) nursing to manage (pt kept ringing) Helped to get urinary Prolapsing, needs. Nurse checked pt if need paracetamol opt to wait to pt seem to be satisfied by approaching Chatted about pain + checked. IV Rad Pt not here (HCA one that went to ↓ in (beg/end) 1 dose at Checked BP/HR, then straight to BL to prep meds 13.00 Nurse took COW + blue tray to day room (3 other pts there) Checked? (returned from HCA) IV infusion finished IB stopped? AW 1 dose Nurse started to prep prepped meds + thoroughly examined Rx 13.00 self-med, gave paracetamol from tray to pt. Left door on Bedside CPM. 1 dose. Penicillin Rx 13.00 "I'll get pop it for you, I may crumble tablet I'm have" to Pharmacy nurse prepped at BL & then gave to pt request (Amoxicillin, Metronidazole, Ferrous sulphate, Paracetamol 1g/5ml) (noticed the nurse crushed pills x 2 for subsequent, think I might be getting her diff - but) MT 111 Rx 13:00 Nurse checked BP/HR, then BL, brought meds to cover like dog urgent Subject to episodic dysphasia triggered + prepped at COW (pt in dressing having female nurse Rachel) injured HCA to help pt take meds JTA 12:00 1 dose Nurse checked BP/HR, ↓ meds from 13:00 then needed pt, assessed wounds took something, then saw nurse Rx 12:00 went to Room 3 to get keys for the other nurse, room (Room stayed out to go into room) - drew bottle water, bottles in & pts thoroughout day round. - then came out pt on tobacco + then O2 had some changes	

Appendix 25 continued



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During | **After**

MAPS form 1 site 503 v1.0
16 September 2012

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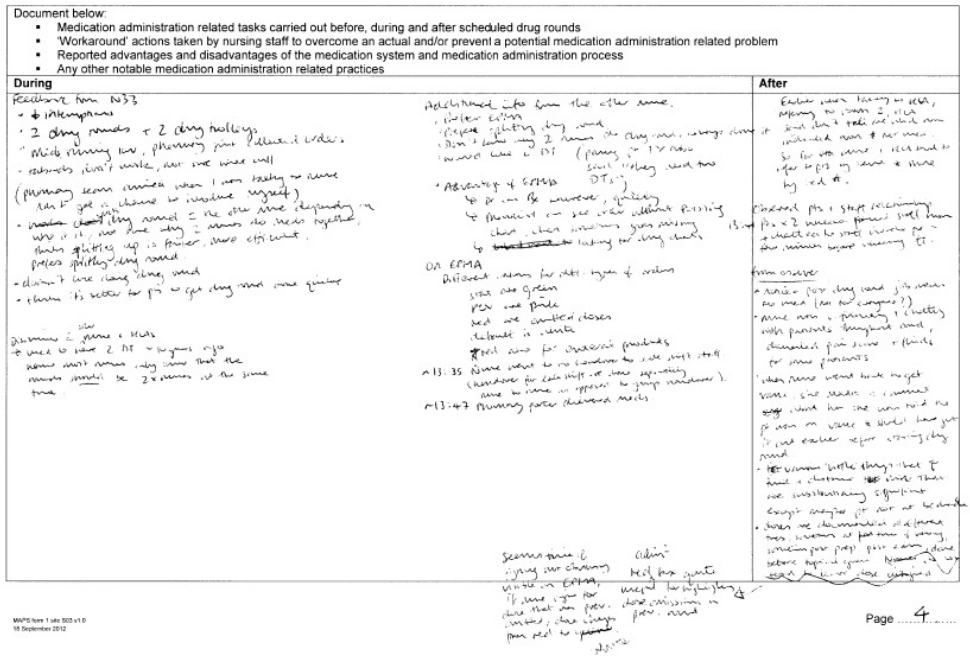

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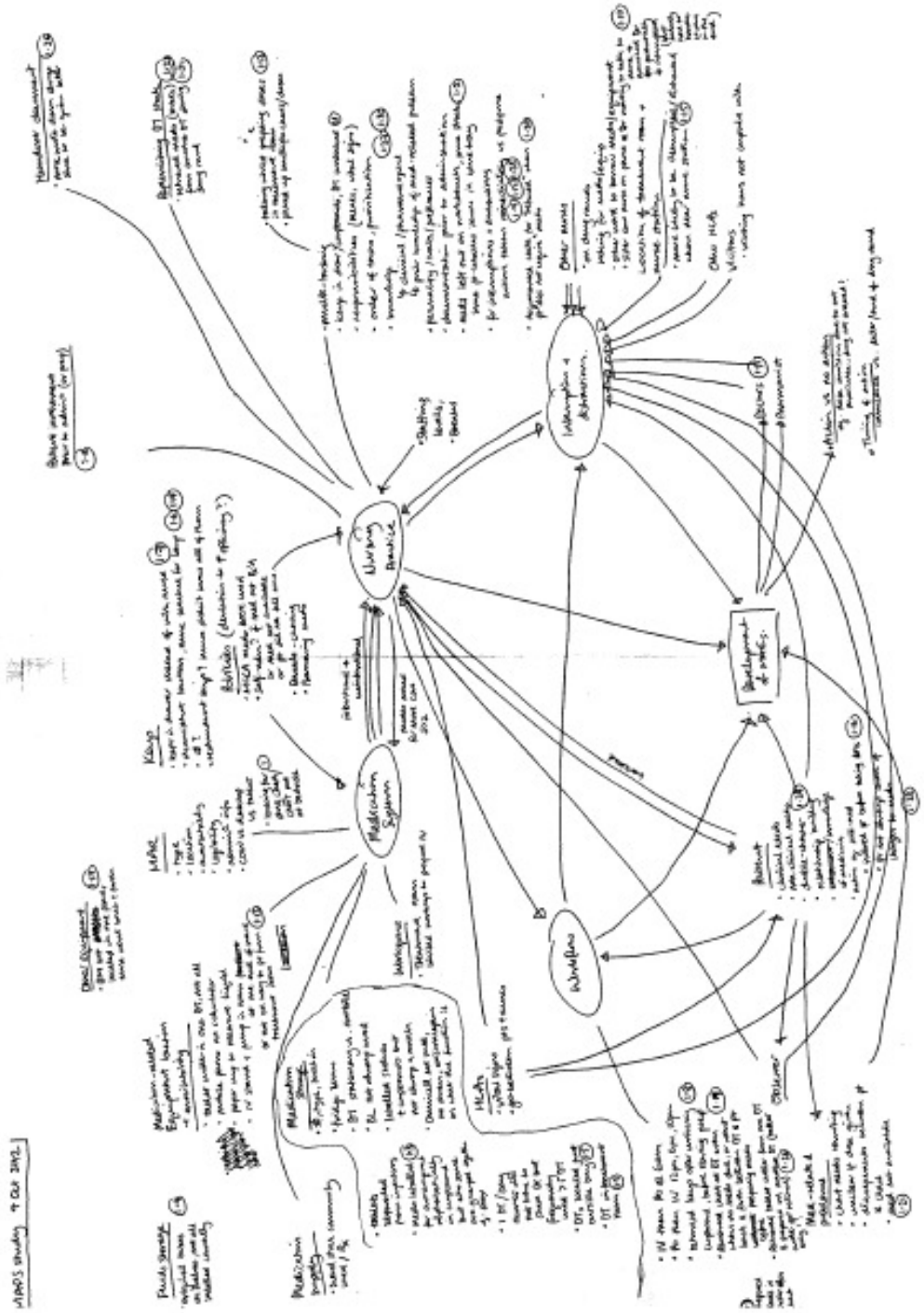
During | **After**

MAPS form 1 site 503 v1.0
16 September 2012

Page 4

Appendix 26 – A sample of photographs taken at site C for the medication administration processes and systems (MAPS) study

Appendix 27 – An example of an expanded thematic framework created during data analysis for the medication administration processes and systems (MAPS) study



Appendix 28 – Examples of items coded under each of the six main themes and 26 associated subthemes were identified from the framework analysis in the medication administration processes and systems (MAPS) study.

Main themes	Subthemes	Examples of coded items
1. Structure of the ward-based medication system and resources available	1.1 Prescribing system	▪ Nurse noticed that the drug chart had still not been recharted. She said she had asked the doctors three times already. Today's doses had been documented outside the administration boxes (DR005, 6pm, lines 440-441, site A)(also coded as 1.2, 2.1, 2.1, 3.4, 4.7) ▪ There are a number of 'screens' for viewing medications, the nurses use a different one to pharmacy staff and doctors (DR019, 12pm, line 25-26, site B) (also coded as 1.2) ▪ EPMA system centrally located at nurse station and (DR039, 12pm, line 2, site C)
	1.2 System for documenting medication administration	▪ Chart was not at bedside, N05 went to the desk and found drug chart (DR005, 6pm, lines 393-394, site A) ▪ When I arrived on the ward, there was one nurse and one HCA at the nurse station. Nurse was checking medicines for a patient on the EPMA at the time (DR021, 6am, lines 225-226, site B) (also coded as 4.7) ▪ CD cupboard located behind NSt, both nurses were there, nurse said "2.5 isn't it?" to the other nurse, the other nurse had gone to the COW and confirmed it was 2.5[ml] (DR019, 12pm, lines 87-88, site B) (also coded 4.3) ▪ There was a large metal drug trolley with a laptop bolted on for drug rounds. There are also two COWs, one at each end of the ward (DR039, 12pm, lines 2-4, site C)
	1.3 Ward-based medication storage	▪ One DT in TR unlocked (lock was unreliable, one nurse thought it was broken, another thought it was fixed) (DR001, 12pm, lines 21-25, site A) (also coded as 4.1) ▪ Nurse disposed of the paracetamol outside C bay then went to D1's bedside cabinet, unlocked top drawer, took the whole drawer containing PODs to the DT (DR022, 10pm, line 391, site B) (also coded 4.7) ▪ Two doses were due, N32 signed for meds, then went to BL, dispensed meds for patient, N30 re-joined. [Noticed N32 pulled the DT instead of pushing – not sure if nurses generally pushed DT but the pulling suggested the DT was quite heavy] (DR043,10pm, lines 523-524, site C) (also coded as 4.3, 4.6) ▪ There were some POD/OSD in DT, and NRT for this patient in DT and nurses (DR042, 6pm, line 439, site C)
	1.4 Patients' own drugs	▪ Next, N09 prepared meds for E, could not find omeprazole 10mg in either DTs, went to pt to ask if PODs had been taken home by his wife. Pt later said "I thought she left the big box here". No meds found at bedside (DR011, 8am, lines 963-964, site A) (also coded as 2.1) ▪ N11 prepared meds at DT first, then went to BL and prepared meds using PODs, skipped tramadol and continued using PODs then went back to DT to prepare tramadol (DR013, 8am, lines 1057-1058, site A) (also coded as 4.6) ▪ She asked the patient if she wanted to take them now. Patient asked if she can take her own as she can't swallow tablets, her own are capsules (DR lines 622-623, site B) (also coded 3.1 and 4.4)
	1.5 Medication ordering system	▪ Nurse went back to the treatment room, looked at chart G6, tried looking again for trimethoprim in the tablet cupboard, couldn't find any, then saw the Sister and asked if they have a stocklist. Found laminated stocklist in pharmacy book, trimethoprim was not ward stock, nurse wrote in the book to order the drug then put chart back (DR005, 6pm, lines 456-458, site A) ▪ Nurse commented on no enoxaparin 20mg, wondered if it had been ordered or if they do not keep it on the ward anymore, commented on ordering as "don't want it missing for tomorrow" (DR024, 6pm, lines 682-683, site B) (also coded as 2.1) (also codes as 4.7) ▪ N18 locked up drug trolley, and went back to the nurse station to answer the phone (it was pharmacy) and ordered hydrocortisone (DR027, 6pm, line 1057, site B) ▪ N28 was multi-tasking, talking to Dr while calling out meds and documenting administration, wrote a note on the jobs list, ordered meds in pharmacy order book (DR040, 6pm, lines 201-202, site C)
	1.6 Policies and	▪ Re tabards, nurse said "no point wearing them" (DR004, 12pm, line 374,

Main themes	Subthemes	Examples of coded items
	guidance	site A) ▪ Ward pharmacy technician told me that the bigger drawer was intended for storing medicines even though he knows some nurses use the smaller drawer for storing meds instead (DR014, 12pm, line 1165, site A) ▪ Nurse told me that if she could change three things, she would have the drug trolleys be fully stocked, bedside locker be fully stocked and have Oramorph® in drug trolley (currently hospital policy at the time was to store it in the CD cupboard (DR022, 10pm, line 456, site B) ▪ Room 3, "is it two and a half baclofen?", "you tell me" N28. The dose prescribed was 25mg = 2.5 x 10mg baclofen tablet. This patient was on level 2 SAM. Earlier the nurse told me that this patient still required supervision, he was on level 1 but now level 2 as he gets distracted. The patient overheard and said he does not (re get distracted) (DR040, 6pm, lines 206-208, site C) ▪ "Pretend we're using the tabard" (DR043, 10pm, line 513, site C)
2. Medication system use in practice	2.1 Actual and potential system-related problems identified by nursing staff	▪ Nurse came across a dose which she knew was not available on the ward (DR002, 6pm, line 147, site A) (also coded as 4.4) ▪ N13 said out loud that the Sister's signature took up too much space (overlapped with next administration box) (DR016, line 1323, site A). ▪ Nurse walked towards C bay, then back to the painkiller cupboard, prepared ondansetron, showed me empty blister that she found in the box (as an example of people not tidying up) and gave keys to the other nurse after she had finished (DR022, 10pm, lines 415-416) (site B) (also coded as 4.6) ▪ N28 noticed the laptop had not been charging and mentioned out loud that she hope there will be sufficient battery (DR039, 12pm, lines 40-41, site C). ▪ Highlighted problem with package changes and understood that it was to do with money but said it can be a problem for them when looking for meds (DR048, 10pm, lines 1129-1130, site C)
	2.2 Problem-led temporary deviations from intended use (workarounds)	▪ Drug chart was full, nurse signed for doses outside administration boxes (DR001, 12pm, line 83, site A) (also coded as 4.7) ▪ Another nurse told the nurse in charge that one of her pts doesn't have a drug chart "shall I let the pt take their own drugs?" Nurse in charge said yes (DR015, 10pm, lines 1273-1274, site A) ▪ N21 showed me an unadministered MST® order that was due at 00:20. She explained that she gave the dose at 11 and because the MST was prescribed every 12 hourly, the next dose was not due yet and the other staff will have to change the timing to give it (DR025, 8am, lines 792-793, site B) ▪ 20:50 N22 started looking on EPMA and printing screen shots (note, not the same as the print out given by previous nurse observed). Nurse told me she preferred this way "saves going backwards and forwards" and noted several IVs as many patients were post-op (DR026, 10pm, lines 882-884, site B) (also coded as 4.7) ▪ Nurse told me that they were supposed to wear 'do not disturb' tabards but said she was too hot to wear it. They are also made of plastic, don't get washed and therefore gets quite dirty (DR039, 12pm, lines 51-52, site C) ▪ EPMA alerted N32 that it was too early (dose due 18:00) and would not let the nurse sign for dose, N32 continued to call out meds and prepare doses, she told me she'll wait (for the system to let her document) but then decided to move on to the next patient (DR051, 6pm, lines 1336-1339, site C) ▪ Laptop had not been plugged in, nurses tried to use laptop but battery was low (it was beeping), so nurses decided to put a selection of meds in a basket and cups, Nutrison®, syringes etc. in another basket and put these on silver temporary trolley. (There was little hesitation, nurses knew what to do, ?done this before) (DR048, 10pm, lines 1049-1050, site C) ▪ Room 6 08:56. Nurse went to the NSt to check obs in patient's folder (NSt was just opposite the patient's room). N28 said to N31 "shall we do it from the POD?" [Nurses referred to the BL as POD] "Not got a table". N28 called out meds, N31 asked if can bring meds out, N28 repeated that there's no table and so N31 prepared the doses from the BL (DR042, 8am, lines 428-433, site C)
	2.3 Non problem-led deviations from intended use	▪ I saw two needles and one syringe attached to a vial of Tazocin® in a blue tray and two unlabelled capped syringes in another tray in the TR unattended, nearby drug chart indicated Tazocin® and co-amoxiclav were due (DR002, 6pm, lines 163-165, site A) ▪ N05 retrieved ketamine solution from the CD cupboard, poured some of the solution into the cap of at bottle and drew up the required dose into

Main themes	Subthemes	Examples of coded items
		two syringes (not coloured) (DR005, 6pm, lines 440-441, site A) ▪ She told me H does meds himself, he has a dosset box and proceeded to sign meds on the desktop PC (DR026, 10pm, lines 960-961, site B) ▪ "You'll notice I'm also not checking wristbands because all the patients have been here for 100 years" N28 told me (DR040, 6pm, line 40, site C) ▪ 09:21. N28 realised the patient was in the bathroom and said "will have to do it because we're very late". N28 then ordered something in the pharmacy book. N31 retrieved meds from the BL and placed it in DT. One dose of Fybogel® was signed as omitted, nurse did not need to look for it, knew they did not have it. N31 took meds to patient in the bathroom, N28 said to leave it by the sink if she had to. Four doses were due and signed (DR042, 8am, lines 455-457, site C) (also coded as 4.7) ▪ Patient was behind curtain and therefore I did not observe. Nurse went behind curtain and then back to DT/TR to sign for meds, knew the other nurse will give Diprobase®, signed for med even though didn't give, signed also for chlorhexidine gel as said patient will get that when they brush his teeth (I saw chlorhexidine mouthwash at bedside not gel) (DR046, 6am, line 860-862, site C)
3. Medication safety	3.1 Patient as a medication problem alert system (for both actual and potential problems)	▪ Pt asked the nurse about a flush, nurse put down the injection and gave approximately 5ml saline flush before administering Tazocin® bolus over approximately 1 min (DR003, 10pm, lines 283-285, site A) (also coded as 3.5) ▪ Pt said there were eye drops in the fridge (DR006, 8am, lines 568-569, site A) ▪ Metformin dose prescribed was 500mg - 1g on chart and prescriber had written 1g OM in additional section of chart for metformin. Nurse had prepared 500mg and given to patient but later corrected it when prompted by the patient and gave 1g in total (DR011, 8am, lines 966-968, site A) (also coded as 3.5) ▪ Nurse went to the bedside with C1 and explained what the tablets were. C1 told the nurse that she takes her own paracetamol, showed nurse and nurse removed the paracetamol tablets from the plastic cup (DR022, 10pm, lines 389-390, site B) ▪ Patient highlighted discrepancy in pregabalin dose, told the nurse it should be 250 twice a day, nurse had 100mg BD, nurse documented this and talked to patient about changes in meds (DR047, 8am, lines 1067-1068, site C)
	3.2 Nurse as a defence for actual and potential medication problems	▪ Day staff noted that F did not get heparin that was prescribed for 8am (chart not signed), asked the night nurse who was still there 07:54. N09 did not see heparin was prescribed BD [neither had I]. Day nurse administered heparin (DR011, 8am, lines 994-995, site A) (also coded as 3.5) ▪ N04 went to H2, prepared paracetamol then realised she had H3's drug chart when she saw metoclopramide and she knew this pt did not have metoclopramide, so went to H3 to finish preparing and administering meds (DR017, 6pm, lines 1376-1377, site A) (also coded as 4.4) ▪ H 15:04 metformin, N18 changed timing to 14:00 on EPMA as she told me that she had asked the doctor to prescribe this in the first place, the patient had self-administered the dose earlier in the day (DR027, 6pm, lines 1083-1084, site B) ▪ 18:00 paracetamol, "on hold", "given 1g in theatre 15:30" record shows theatre staff documented this at 15:45 (DR027, 6pm, line 1090, site B) ▪ N28 remembered the patient was on vancomycin, could not see it on EMAR, I intervened, N28 saw it but there were two medication orders for vancomycin, both for vancomycin 125mg capsule QDS but one had a red box indicating dose has not been given and it was past the scheduled time (06:00) and on the other one, someone had written "liquid" under the medication order [?pharmacist]. I could see there was liquid in the DT. Dose was prepared (DR042, 8am, 430-433, site C)(also coded as 2.1, 3.5, 4.3) ▪ N34 went through meds, saw vancomycin liquid prescribed for 6am not given, N34 was not sure about this, discussed it with N33 and decided to ring the night nurse to confirm whether or not a dose had been given. [night nurse confirmed the dose had been given] (DR047, 8am, lines 956-957, site C) (also coded as 3.4 and 4.3)
	3.3 Actual and potential inappropriate prescribing and prescribing	▪ Nurse thought tinzaparin 24,000 units was unusually high, knew there was a dosing chart on the SCR so went there to check, but it did not go beyond 23,000 units, so nurse asked the Dr and left drug chart with him as Dr was also uncertain and needed to clarify (DR002, 6pm, lines 145-146, site A) (also coded as 4.6)

Main themes	Subthemes	Examples of coded items
	errors	▪ Route of administration unclear on medication order, nurse asked pt which eye the eye drops was for, pt said both eyes and that he usually apply it in the morning and not at night nurse said she will get it changed and did not administer the dose [unclear if nurse knew that Xalatan® is usually administered in the evening and not in the morning] (DR003, 10pm, lines 182-185, site A) ▪ Procal shot prescribed as "T", nurse told student it should be 30ml (DR004, 12pm, line 332, site A) ▪ Nurse asked B2 about his pain, he reported that it was very sore. Nurse told the patient what she was giving (included naproxen and omeprazole), patient explained he takes both at night: "only take it at night" "not morning?" "only take it at night" "ah they prescribed it for this morning…..I don't know why [they] prescribed it for morning" explained to patient that she did not give these last night and so patient took the meds this morning (DR021, 8am, lines 288-291, site B) (also coded as 3.1) ▪ Pre-drug round - 20:30 Nurse spotted that C5 and C6 did not have enoxaparin prescribed. She queried this with the nurse in charge of the previous shift (who was still on the ward at the time) and asked if the doctor was here and whether or not they need the surgical doctor to prescribe (DR026, 10pm, lines 879-880, site B) ▪ Both nurses checked the observation chart, N28 then looked at the system for vancomycin and found that it was not prescribed yet, placed order in pharmacy book, asked Dr for dose, Drs were not ready to prescribe, they were still assessing the patient to see if vancomycin was needed (DR040, 6pm, lines 207-208, site C) ▪ Nurse checked EMAR, knew/expected vancomycin, looked for it on the screen, saw that it was not scheduled for 22:00 (was scheduled for 06:00, 12:00, 18:00, 00:00) (DR043, 10pm, lines 537-538, site C). (also coded as 4.4) ▪ N28 identified a potential prescribing error, the patient was prescribed clindamycin and erythromycin, paused, then N29 re-joined the DR, N28 called out meds while N29 looked in BL inside the room (not observed while in room, but I could hear the conversations). N28 saw a Dr nearby and asked Dr to stop the clindamycin [self-initiated interruption] (DR040, 6pm, lines 194-197, site C)
	3.4 Actual and potential strategies to increase medication safety	▪ 19:38 I found out from Sister that they have been tightening down on omissions by introducing a drug chart check on handover. The nurse has to go through the drug chart with each other to account for all the doses due during the shift (DR008, 6pm, line 807, site A) ▪ 'N11 told A3 that she will come back to give gliclazide after breakfast arrives (DR013, 8am, line 1059, site A) ▪ After the drug round, N18 went through each patient systematically to check all the doses had been signed for, signed some doses that had not been signed for earlier (DR022, 10pm, lines 436-438, site B) ▪ Nurse went through her thought processes with me and her routine of double checking patient's medicines on the desktop PC after the drug round to check whether or not her patients had had fluids prescribed. She wanted to make sure she was prepared for patients that had just had an operation in case their observations showed a drop (? Fluid ? BP), implying that she expected to see IV fluids prescribed and if not, then she would follow this up by handing over to the other nurses [I think this nurse may be a bit reluctant to contact the prescriber directly, possibly because she is 'bank', maybe because she knows she is not familiar with the teams and/or because she prefers to let the regular nurses know what is going on] (DR024, 6pm, lines 688-693, site B) (also coded as 4.4) ▪ N34 told N33 that a patient's baclofen was missed at 6am, said they will need to tell nurses that there are a few 6am doses to administer (DR047, 8am, lines 998-999, site C) ▪ 08:36 Room 8. N33 asked the patient to tell her what she needed, N33 would get them out. Patient called each drug by generic name, N33 took them out from the BL, N34 signed (DR047, 8am, lines 933-934, site C) ▪ 17:10 room 8. "What do you need?" N34 greeted the patient and asked patient to tell her what meds she needed (?to test patient, general conversation?). Patient started listing her meds "oxybutynin, bisoprolol, green antibiotic, enoxaparin" (patient pronounced names of meds well). N34 went to the BL (located on the left side of the patient, furthest away from centre of room and had little space), retrieved meds, then went to the EMAR to sign for administration, "do you need zinc as well?" N34 asked the patient, "yes , sorry", N34 went back to the BL to retrieve drug for the

Main themes	Subthemes	Examples of coded items
		patient to self-administer (doses were not confirmed but there had been no changes from yesterday) (DR045, 6pm, lines 738-742, site C)
	3.5 Actual and potential medication administration errors	▪ This time the Tazocin® had not fully dissolved and there was still powder left at the bottom of the vial. The nurse drew up what she could and administered it to the patient B5 over approx. 1min, flushed approx. 5ml post bolus (DR003, lines 277-279, site A) ▪ Back at B5 bedside, nurse realised she had picked up another patient's eye drops by mistake (same drug), told pt and went back to fridge to get B5's eye drops, she had seen it earlier and wasn't sure why or how she picked up the wrong ones (DR006, lines 570-571, site A) ▪ I think the nurse must have asked the patient about painkillers earlier on (~12pm) and so knew A1 did not require any painkillers, because the nurse did not go to A1 but did document "not given" against medication order for paracetamol and 'patient refused the medication' for diclofenac (DR023, 12pm, lines 557-560, site B) ▪ N28 signed EPMA for doses given while the other nurse prepared and started PEG admin, noticed some 8am meds not signed, walked over to a different nurse (same bay), whispered something, then came back to DT, paused, was about to sign, the other nurse said she can do it, N28 paused and then said she will let her sign it later, then saw an enteral supplement was due, offered the patient different flavours, returned what was not needed to DT, back to patient, gave enteral supplement to patient, momentarily distracted by the other nurse (was still administering the carbocisteine down PEG) (DR039, 12pm lines 92-96, site C) ▪ Five doses were due, one was omitted due to drug not being available (erythromycin) (DR043, 10pm, line 535, site C)
4. Workflow (factors that influenced workflow)	4.1 Medication ordering, replenishing, and security	▪ Drug not available, nurse borrowed meds from another ward (seemed to be routine) (DR003, 10pm, line 200, site A) (also coded as 2.1) ▪ N04 went to find keys for SCR found no Tazocin® in cupboard, placed telephone order for 15 vials from pharmacy, then went to the ward next door and borrowed 5 vials (DR004, 12pm, lines 360,361, site A) ▪ N07 prepared 2 doses then asked patient if they wanted a laxative, pt said no, N07 documented "6" [code for patient refused, "5" is the code for not required by patient] in chart then prepped 2 remaining doses (DR009, 6pm, lines 825-826, site A) ▪ Bedside cabinets next to each patient, PODs are stored in the unlocked drawer at the top of the cabinet (DR019, 12pm, lines 5-6, site B) ▪ Pre-drug round, nurse opened the drug trolley, went through the medicines, putting empty boxes and blisters in the plastic bin bag attached to the drug trolley and replenished tramadol from the stock cupboard (asked another nurse who was at the nurse station to get the box for her) (DR022, 10pm, lines 353-354, site B) ▪ Before starting the drug round, nurse looked through the drug trolley and replenished it with medicine pots and purple enteral syringes (DR039 12pm round, line 45, site C)
	4.2 Medication administration support from and to other health care professionals	▪ Nurses worked together, verbal communications were sometimes very brief "vancomycin for B1", "waiting for level" (DR001, 12pm, lines 28-30, site A). ▪ Meds prepped from both DTs, asked HCA "did you do my BMs?" when came across metformin prescribed. BMs had not been taken, the machine was broken and the HCA was in the process of finding another one (DR011, 8am, lines 964-966, site A) ▪ Then asked a nearby nurse the drug name on the chart as she could not read the doctor's handwriting. The other nurse confirmed it was dihydrocodeine (DR016, 12pm, lines 1323-1325, site A) ▪ Nurse then walked round to the drug trolley, helped another nurse look for meds before going back to the cupboard to look for gabapentin for the other nurse (DR022, 10pm, lines 416-417, site B) ▪ Nurse went back to the NSt PC, checked meds due for B5, got interrupted by another nurse who wanted a double sign for fentanyl (noticed both nurses tend to sign before giving) (296-297) (DR021, 8am, lines 296-297, site B) ▪ Room 4, N28 "out of [patient's name] cupboard, gabapentin 400" that's the lot, to the other nurse [Nurse signing for meds is different to nurse preparing meds, Nurse preparing meds rely on the other nurse to read out medication order] (DR039, 12pm, line 90, site C) ▪ The other nurse (the one that was supposed to be on the drug round) started using the COW and prepped meds ahead of N28. When N28 signed on, she found the doses had been signed for already then moved on to the

Main themes	Subthemes	Examples of coded items
		next patient. This happened twice, then N28 said she could not work like this [she was losing track with which patient had been given meds], and asked the other nurse to check meds in the BL while N28 looked for meds in DT and worked together for the last few dose (DR039, 12pm, lines 99-101, site C) (also coded as 4.3, 4.5, 4.6, 4.7) ▪ N33 "[patient's name] when the girls are done with you can you call me to put the cream on?" HCA said she can do it, N33 told HCA where each of the two creams needed to be applied (DR047, 8am, lines 917-918, site C)
	4.3 Staff expectations, use of prior knowledge, and information transfer	▪ Paracetamol was prescribed "po/iv" with IV circled, nurse prepared tablet after checking handover sheet and pt's temperature chart (DR001, 12pm, lines 70-71, site A) ▪ Nurse knew drug was not available in advance and took no further action on drug round to retrieve drug (DR002, 6pm, line 122, site A) ▪ Nurse went straight to bedside locker and found a bag of PODs, did not look in the DT at all (DR003, 10pm, lines 179-180, site A) ▪ While the nurse was preparing meds for B2 earlier, B1 had arrived on the ward from theatre. The nurse told me this patient probably won't need any meds now. She will hold off tramadol for B2 as patient is nauseous and told me that this patient had a hernia operation and therefore did not want to give tramadol in case it makes him sick and make him "heave" (172-174) (DR020, 6pm, site B) (also coded as 3.4 and 4.4) ▪ Patient asked the nurse about her aspirin, said she hasn't taken it today. Nurse stopped what she was doing to talk to the patient. Patient said nurse last night gave her an injection to replace the aspirin, nurse confirmed that she will also give the injection (DR024, 6pm, lines 627-629, site B) (also coded as 4.4) (also coded as 3.1) ▪ N28 set up the nebuliser but was missing the connecter "where has the air thingy gone" and then went to search for it in room 2, retrieved it from another patient's bedside, and set it up. [Quite a narrow space to get behind patient to air socket on wall] (DR039, 12pm, lines 96-98, site C) ▪ N32 worked through the prescribed list, saw ketoconazole shampoo not signed at 18:00, nurse signed retrospectively and said she had given it earlier. N32 told N30 that she just need gabapentin 400 (indicating for N30 to retrieve this from the BL). N30 took the liquid meds and went to the BL. "Not bladder washout every night is it?" N32 said out loud to N30, N30 confirmed that it was not for every night and that the patient had it last night. There was no gabapentin in the BL, N30 remembered a patient in room 5 had some but was gowned up so N32 went to borrow dose from another patient (DR043, 10pm, lines 552-557, site C) (also coded as 3.5, 4.2, 4.4, 4.6) ▪ 22:07 room 3. N32 looked up meds on EMAR, then went straight to the BL and prepared meds from there. Two doses (DR043, 10pm, line 559, site C)
	4.4 Patient's clinical status, needs, and requests	▪ 'Pt insisted he should also be having another small tablet, (gliclazide was prescribed for 6pm not 12pm), nurse eventually gave pt the gliclazide (DR001, 12pm, lines 64-66, site A) ▪ N14 tend to look at the drug chart first before starting to prepare meds. She introduced herself to the pt, asked the pt if they were still taking the ointment for the nose, pt said no, N14 asked why and pt explained he doesn't have any, the tube is empty (DR018, 10pm, lines 1485-1486, site A) ▪ Nurse asked the patient about paracetamol and tramadol, patient just wanted paracetamol, not tramadol and agreed to taking cyclizine after the nurse explained that it was not a painkiller but a replacement for the other anti-sickness (DR024, 6pm, lines 644-645, site B) ▪ Pre-drug round - 16:43 N18 checked on the EPMA for painkillers for a patient that approached her at the NSt (1013). Nurse18 asked another nurse to help and give the painkillers (because she was dealing with a patient's discharge, D3) (DR027, 6pm, lines 1043-1044, site B) ▪ N30 told me that bisacodyl is due at 8am but she was not going to give, day staff to give. However, if the patient was due to have physio then she would have given it, and explained that it was important to do so to ensure the patient opens their bowels before therapy. N30 administered chlorhexidine mouthwash using a lollipop sponge and applied it to patient's lips and gums (DR041, 6am, lines 344-346, site C) (also coded as 4.6) ▪ N35 asked the patient if he needed paracetamol, patient said yes, she asked if he was in pain, he said no, "so why do you need paracetamol?", nurse talked to patient as she prepared the meds and discussed not taking paracetamol now but to let her know if he needs it later, asked patient to cut tablet in half (patient due to be discharged), nurse asked the patient to let her know when he's ready to take the meds as she wanted to check his

Main themes	Subthemes	Examples of coded items
		swallow (DR047, 8am, 1075-1078, site C)
	4.5 Shared resources required for medication administration	▪ Nurse looked for drug charts, Dr had drug chart, nurse waited (DR001, 12pm, line 88, site A) ▪ Searched for keys to SCR, asked nurse in charge and looked in drawer (540,567). Borrowed IV co-amoxiclav from another ward (DR006, 8am, lines 542-543, site A) ▪ Nurse then went over to B2 and explained to me that she would normally bring the chart to the patient but because the other nurse was using it, she didn't do it on this occasion) ['chart' meant EPMA in this situation] (DR020, 6pm, lines 161-162, site B) ▪ Nurse moved to another PC as the other nurse wanted to use the same PC (DR021, 8am, line 300, site B) ▪ The other nurse (the one that was supposed to be on the drug round) started using the COW and prepped meds ahead of N28. When N28 signed on, she found the doses had been signed for already then moved on to the next patient. This happened twice, then N28 said she could not work like this [she was losing track with which patient had been given meds], and asked the other nurse to check meds in the BL while N28 looked for meds in DT and worked together for the last few doses (DR039, 12pm, lines 98-101, site C) ▪ 22:27 N32 checked meds, prepared liquid from the DT, gave to patient then went to the BL to get neb. N30 went to give meds via PEG to the patient. Another patient also needed neb (nurses only had one nebuliser connector device? "Air thingy"). Interruption – looking for "air thingy", should be two but only have one currently. N32 said that's it (confirming that there was only one currently available) (DR043, 10 pm lines 583-585, site C) (also coded as 4.6 and 5.1)
	4.6 Individual nurses' approach to medication administration tasks (order of activities)	▪ Nurse prepared IV prior to starting the non-IV drug round (DR001, 12pm, lines 35-40, site A) ▪ N09 went to the kitchen to get Ensure® when she came across the medication order on the chart (instead of writing down and retrieving it at the end of the drug round) (DR011, 8am, lines 959-960, site A). ▪ Nurse went back to the computer to look up other meds due, went to the treatment room and prepared G5%, went back to the NSt to document the batch number and expiry of G5% on EMAR (explained to me that she could use the details from this bag as it came from the same box as the G5% she put up earlier (DR021, 8am, lines 307-309, site B) ▪ Nurse checked on the system what dose of tramadol the patient had previously (100mg) and prepared 100mg (patient was prescribed 50-100mg) and entered "given PO" on the system. She then went to C3, greeted patient and asked about their pain and told patient what the medications were in the plastic cup (DR026, 10pm, lines 889-892, site B) ▪ 18:00 paracetamol 1g PO/PR/IV signed not given 19:00 [but I know nurse had asked patient before 18:00] (DR020, 6pm, line 213, site B) ▪ There were seven doses due including three creams, N32 explained she signed for it as the patient will put it on later then N30 went to the day room to give the patient his meds (DR043, 10pm round, lines 524-525, site C) (also coded as 4.7) ▪ N28 asked the patient if she wanted Laxido®. N29 prepared the Laxido® whilst N28 prepared enoxaparin from the DT. The nurses were very quick and both were preparing meds at the same time so it was quite challenging to observe and keep track of meds that had been prepared, signed etc. N28 signed for enoxaparin and added an extra comment "checked by [N29's name]" on the EMAR (DR040, 6pm, lines 189-191, site C)
	4.7 Actual and potential strategies to streamline workflow or increase efficiency	▪ Nurse checked whether or not observations had been done prior to drug round (DR001, 12pm, line 54, site A) ▪ Nurse reconstituted multiple vials of Tazocin® "it will probably take about 20 min before it dissolves" and then prepared vancomycin and metronidazole (both for the same pt) whilst waiting for Tazocin® to dissolve (DR003, 10pm, lines 243-246, site A) ▪ Sometime between 17:20 and 18:00 she had checked with B5 about their pain and the patient did not require any analgesics so no meds were needed for this patient (DR020, 6pm, lines 165-166, site B) ▪ Nurse then retrieved paracetamol and diclofenac from cupboard (cupboard not locked throughout drug round, nurse explained she will lock it after as still got "bits and pieces" to do) (DR021, 8am, lines 296-298, site B) ▪ Before starting the drug round, the nurses opened DT, logged on to laptop, retrieved two bottles of medicine from the fridge and placed inside DT (DR043, 10pm, line 513, site C)

Main themes	Subthemes	Examples of coded items
		▪ N36 asked HCA if she could give meds to the patient (meds that had already been prepared) (DR050,12pm, line 1251, site C)
5 Interruptions and distractions	5.4 Sources of interruptions and distractions	▪ Another nurse interrupted N08 and asked her if she had seen a patient's VAC dressing leads (DR010, 10pm, line 905-906, site A) ▪ N04 then got interrupted by a Dr and then by a pt walking past. Afterwards, she said "I hate it when I get distracted when I'm doing medicines" [N04 was looking for the pot of medicines for G3 that she had earlier] (DR017, 6pm, lines 1412-1414, site A) ▪ Nurse was interrupted by HCA whilst giving meds, then continued talking to HCA and clicked screen to view the next patient's meds at the same time (DR019, 12pm, lines 61-62, site B) ▪ As nurse finished and started to wheel COW and drug trolley out of D bay, HCA came over and asked if the nurse was still doing the meds, and if so, she will come back to ask her a question afterwards, nurse said yes but then asked why, HCA told her about a phone call regarding a patient and nurse dealt with query with HCA there and then[there is recognition that the nurse should not be interrupted during the drug round but it is not always clear when a nurse is still on the drug round or not and the nurse may allow/encourage interruptions?] (DR019, 12pm, lines 101-104, site B) ▪ Dr interrupted nurses, noting nurse did not have a tabard on. Drs knew not to interrupt and explained they knew they shouldn't interrupt the nurse even though she didn't have her tabard on. Nurse explained she was menopausal and it was too hot to wear the tabard. Dr called out to nurse that he had discontinued the clindamycin, nurse said not discontinued on the system, Dr said the nurse needs to refresh the screen, nurse said she will do it later (DR040, 6pm, lines 198-201, site C) ▪ Outside room 7, nurse told me the keyboard was too high to type; screen was too low and small. She said she had lots to 'moan' [re EPMA] about whilst continuing to check meds due on the EMAR (DR039, lines 76-77, site C)
	5.5 Time and location of medication administration	▪ Opportunistic interruption by another nurse whilst N03 was in TR retrieving fludrocortisone for pt on drug round (DR003, 10pm, lines 197-199, site A) ▪ Whilst in the TR, N05 noticed the phone had been ringing for a while and said she suspect it is the 'CathLab' (chasing her?), N04 suggested that N05 finishes her meds first before dealing with Cathlab or otherwise it will not get done (DR005, 6pm, lines 461-463, site A) ▪ 06:53 Nurse started non-IV drug round by looking up the patient's meds on the desktop at the NSt. She was interrupted by the pre-admission nurse regarding a handover and staffing. Nurse started to read the EMAR whilst talking to the pre-admission nurse, checked 08:00 meds that were due (DR021, 8am, lines 276-278, site B) ▪ Whilst at the computer, the nurse was given the phone by another nurse who was on another phone (with pharmacy to request more gabapentin stock) (DR022, 10pm, lines 423-424, site B) ▪ N33 took COW and blue tray to the day room and gave meds to the patient. There were three other patients in the day room having their lunch with assistance from the HCAs (DR044, 12pm, lines 627-628, site C) ▪ Nurse greeted various staff as they walked past whilst looking up meds on EMAR (DR056, 8am, line 1751, site C) ▪ 17:15 N20 logged in to desktop EPMA, started going through medication screen. Dealt with telephone query in between and engaged in discussions with colleagues whilst going through meds (DR024, 6pm, lines 593-594, site B)
	5.6 Nurses' role, responsibilities, and relationships	▪ Nurse asked some pts if they wanted painkillers but not all (DR001, 12pm, line 76, site A) ▪ Kitchen staff told the nurse the food was getting cold, nurse was responsible for giving out food (DR002, 6pm, lines 125-126, site A). ▪ Then a hospitality staff interrupted, asked the nurse if F is NBM and the nurse confirmed that he is due to be NBM from midnight not now. Straight after, the HCA came over and asked the nurse if C4 can eat (initially a distraction, then turned into an interruption when the nurse stopped what she was doing) (DR024, 6pm, lines 653-655, site B) ▪ Interruption by student nurse regarding C4. Nurse dealt with query "because her blood pressure is going down, we just need to keep the cannula in case we need to give her fluids" (DR024, 6pm, lines, 629-630, site B) ▪ N28 asked HCA if she was okay (HCA was hovering), nurse talked to HCA whilst on screen to next patient's meds (NR) whilst at pt's bedside (DR050, 12pm, lines 1271, site C)

Main themes	Subthemes	Examples of coded items
	5.7 Actual and potential strategies to manage interruptions and distractions (also coded as 5.1)	▪ G4 interrupted to ask for codydramol, N03 acknowledged then carried on looking at chart at DT (DR007, 10pm, lines 631-632, site A) ▪ Ward seemed fairly quiet except for phones ringing. Nurses generally did not answer phones straight away even if they were next to the phone - it depended on what they were doing at the time (DR012, 12pm, 1003-1004, site A) ▪ Nurse was interrupted by other nurses at the NSt whilst preparing meds, brief conversation before continuing to prepare meds (multi-tasking) and putting meds away whilst still talking to the other nurses (DR023, 12pm, lines 521-523, site B) ▪ As the nurse tried to leave C3, C4 interrupted and asked the nurse to remove her Venflon®. Brief discussion, nurse explained that she still had meds to give and will come back to see her later (DR024, 6pm, lines 669-670, site B) ▪ N28 was multi-tasking, talking to Dr whilst calling out meds and documenting administration, wrote a note on the jobs list, ordered meds in pharmacy order book. 17:42 "Right I'm all yours" to Drs, N28. Drs told N28 that the dose of levetiracetam had been reduced, diazepam PRN was added for one patient. For another patient, peppermint oil capsule had been started and for a third patient, vancomycin had been started. (Drs were on their ward round) (DR040, 6am, lines 201-204, site C)
6 Observer-related effects	6.4 Actual and potential effects of the presence of an observer on nurse/other staff/patient behaviour	▪ Pt asked why N12 was asking for his name when he knew she knows it (DR015, 10pm, line 1214, site A) ▪ N11 talked a little as she was preparing meds, difficult to know if this is what she does or whether she did it for my benefit. She did say later that she did everything the same as normal and did not really notice that I was there (DR013, 8am, lines 1080-1081, site A) ▪ Later on, I saw N07 going to prepare IV meds, I thought she was going to go back and do 2pm oral drugs but she wasn't and said she was feeling uncomfortable with being watched so I stopped the observation (DR014, 12pm, lines 1133-1134, site A) (also coded as 4.6) ▪ N21 described the drug round as normal. She said it was okay being observed but also said she was a bit anxious (DR025, 8am, line 852, site B) ▪ This nurse talked to me throughout the drug round, even though I had told her the same thing as the others, I think she just finds it more natural to talk to me than to pretend I'm not there. She usually talked to me when preparing meds in the treatment room, showed me some of the vials. I find it more difficult not to talk to the nurse when in the treatment room as there is nobody else there. I also know this nurse is a chatty nurse from having met her on previous rounds (DR026, 10pm, lines 930-933, site B) ▪ Outside room 7, nurse told me the keyboard was too high to type, screen was too low and small. She said she had lots to 'moan' [re EPMA] about whilst continuing to check meds due on the EMAR (DR039, lines 76-77, site C) (also coded as 2.1) ▪ N32 asked me how to pronounce levetiracetam and then told me "I always say Keppra®", asked if that was a brand name whilst documenting administration for the patient (DR051, 6pm, lines 1354-1355, site C)

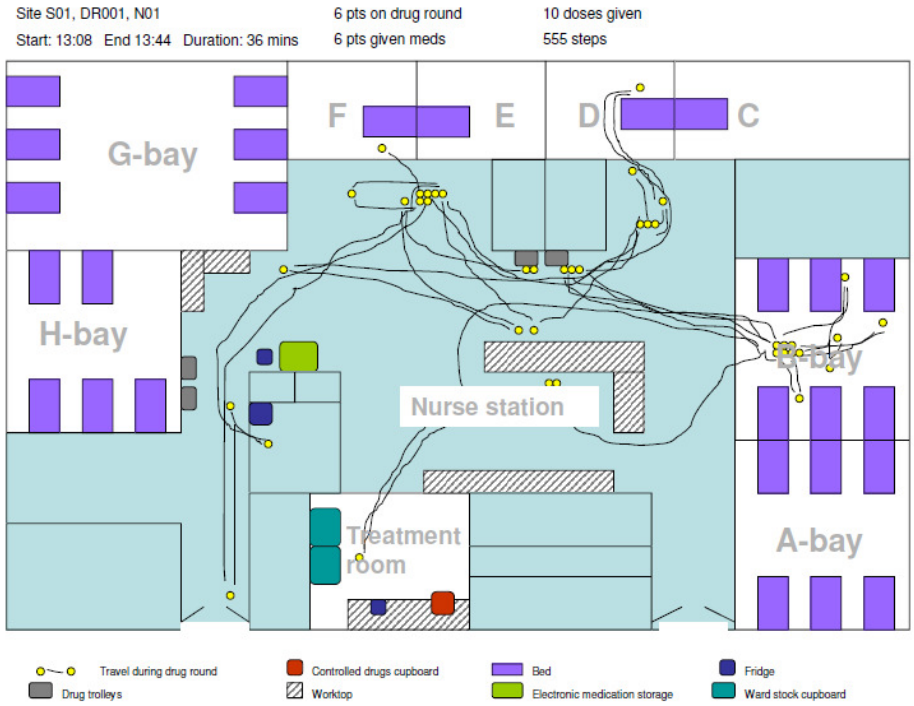
***Abbreviations**: BD, 'bis in die' meaning twice daily; BL, bedside medication locker; BM, refers to measuring blood sugar; CD, controlled drugs; COW, computer-on-wheels; Dr/Drs, doctor/s; DT, drug trolley; EMAR, electronic medication administration record; EPMA, electronic prescribing and medication administration system; G5%, glucose 5%; HCA, health care assistant; IV, intravenous; meds, medicines; neb, nebule; NBM, nil by mouth; NSt, nurse base station; NRT, nicotine replacement therapy; Oramorph®, morphine sulphate oral solution; PC, personal computer; PEG, percutaneous endoscopic gastrostomy; PO, 'per os' meaning orally; PR, per rectum; PRN, 'pro re nata' meaning 'when required; Pt, patient; QDS, 'quarter die sumendus' meaning four times a day; SAM, patient self-administration of medication scheme; SCR, stock cupboard room (synonymous to TR); TR, treatment room.*

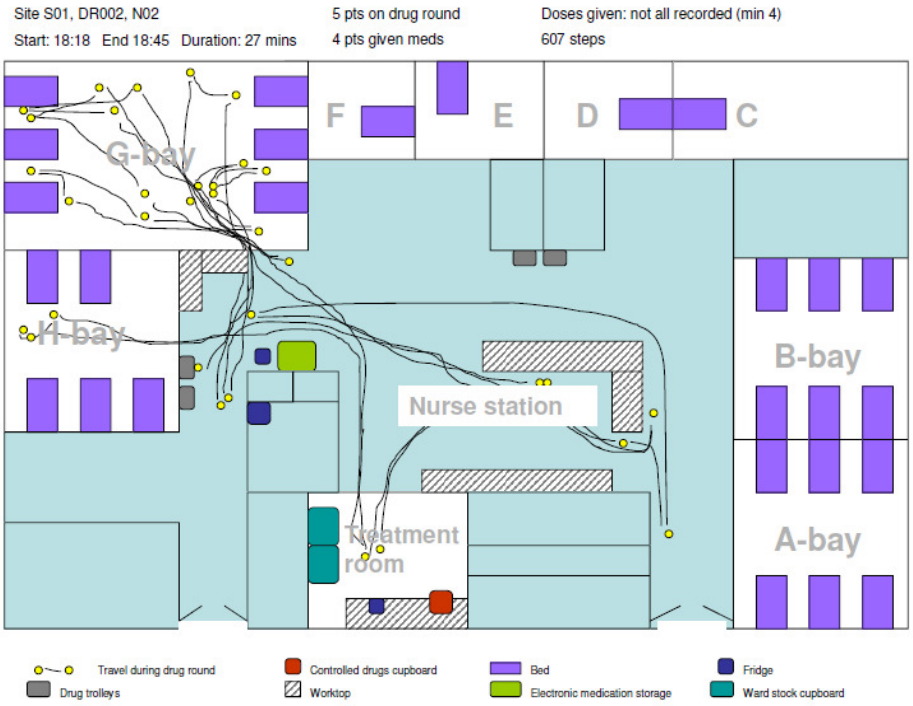
***Codes**: DR(number), drug round identifier code; N(number), nurse identifier code; some patients are referred to according to their bed number which was documented as a single letter or a single letter with a number.*

***Branded drugs**: Diprobase®, a branded emollient; Ensure®, a branded dietary supplement; Fybogel®, isphagula husk; Keppra®, levetiracetam; Laxido®, macrogol; MST, morphine sulphate tablets; Nutrison®, a branded dietary supplement; Tazocin®, piperacillin and tazobactam; Venflon®, a cannula; Xalatan®, latanoprost.*

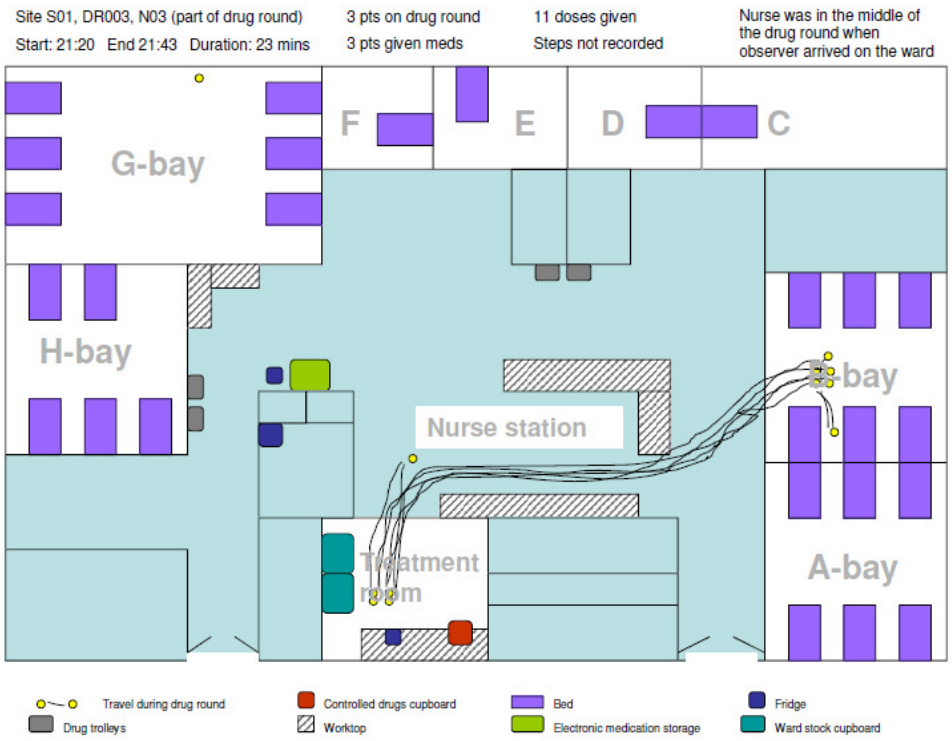
***Other**: [ ] indicate additional thoughts from observer MM made at the time of observation.*

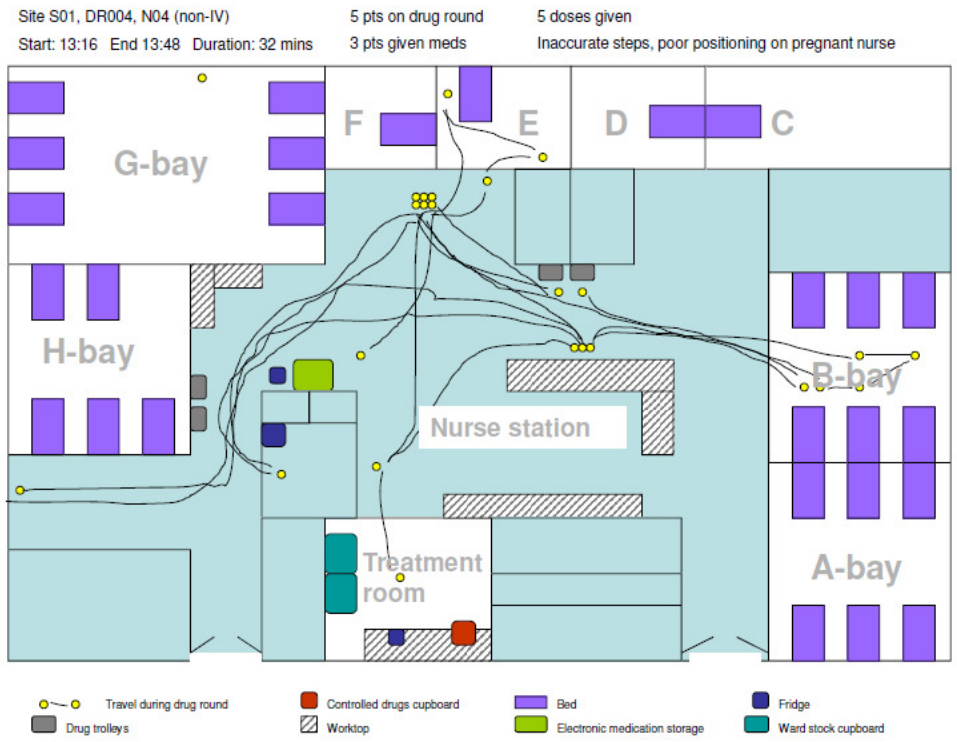
Appendix 29 – Maps of travel by the nurse during drug rounds observed at site A for the medication administration processes and systems (MAPS) study. S01, site 1; DR[number] indicates drug round code; N[number] indicates nurse participant code; pts, patients.



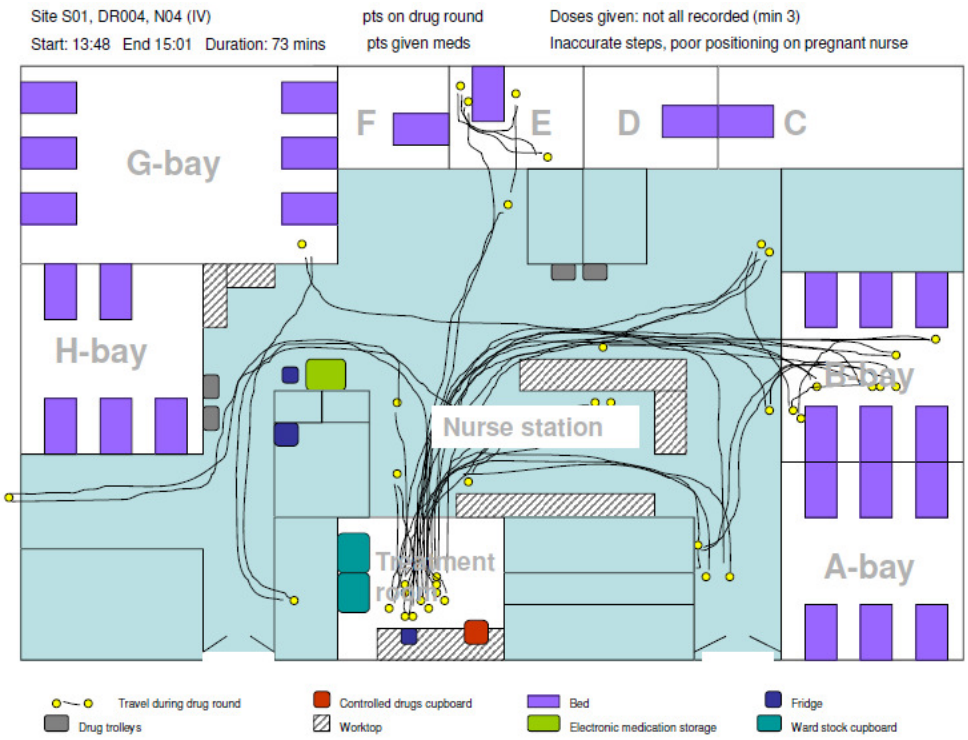


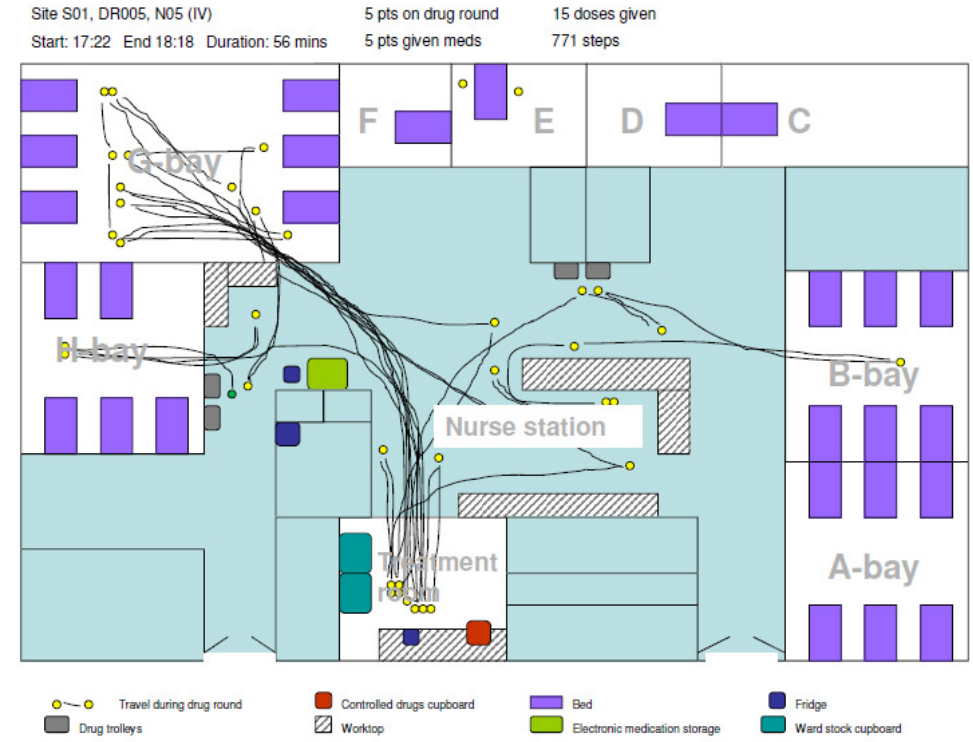
Appendix 29 continued



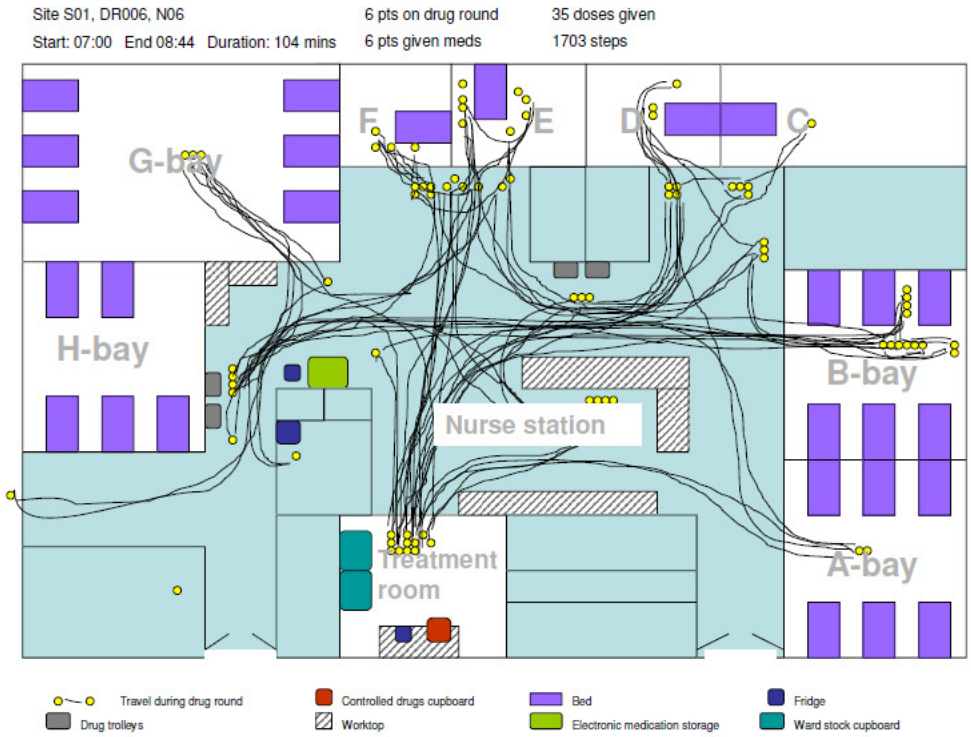


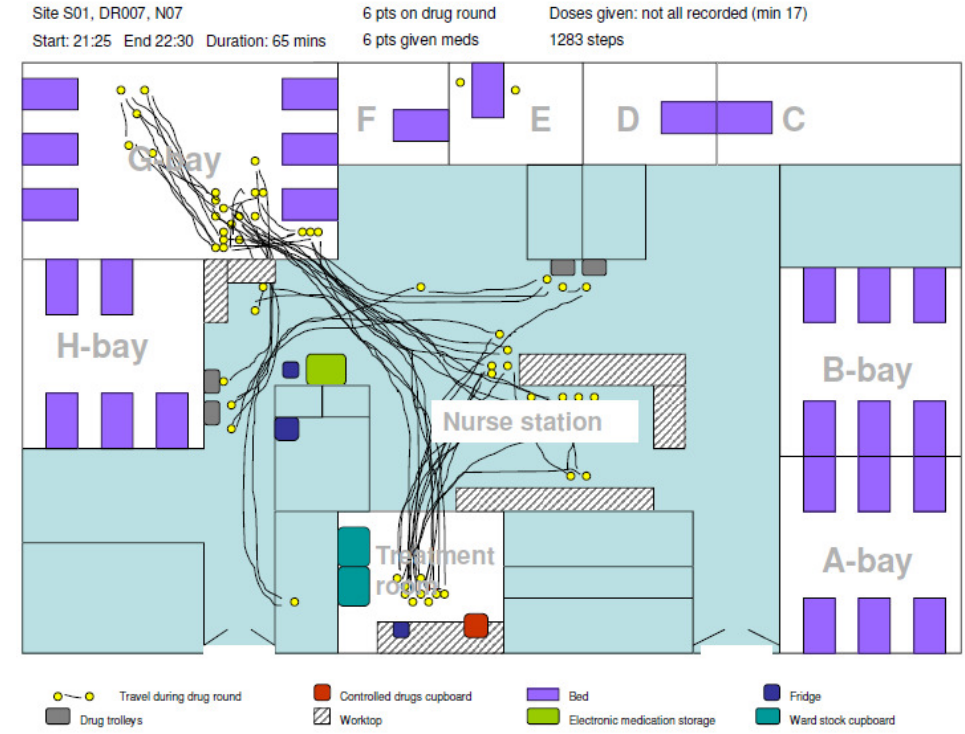
Appendix 29 continued



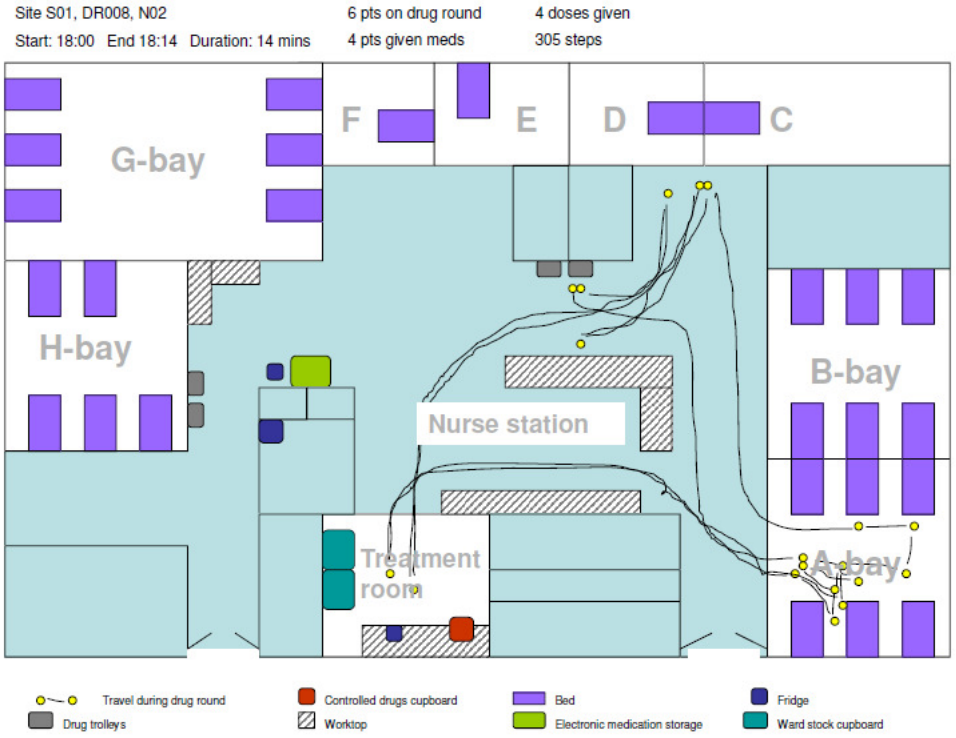


Appendix 29 continued

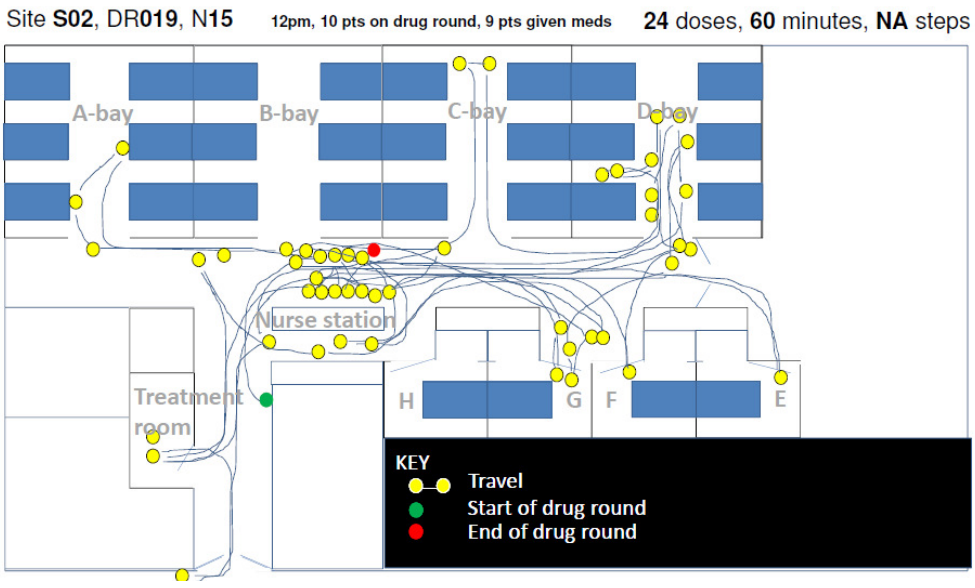




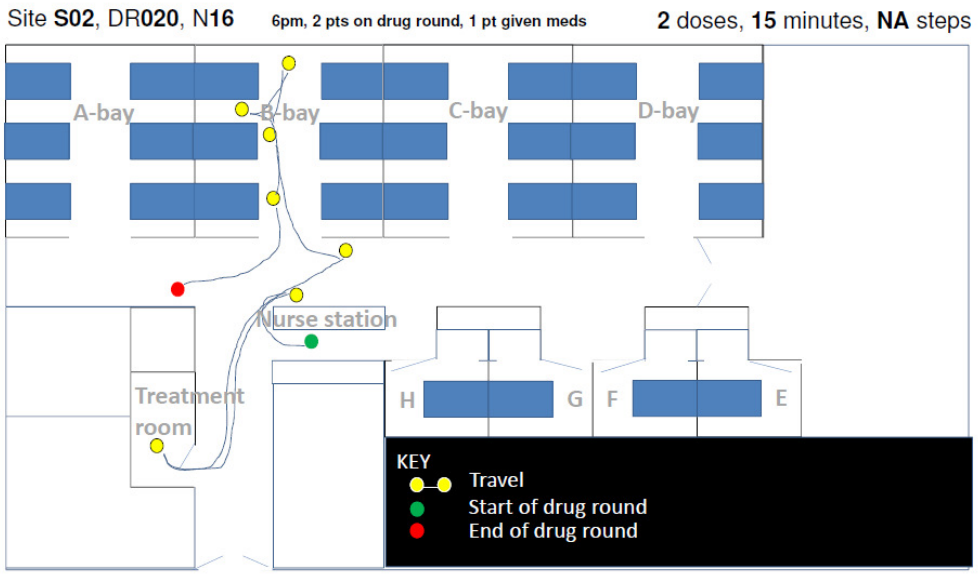
Appendix 29 continued

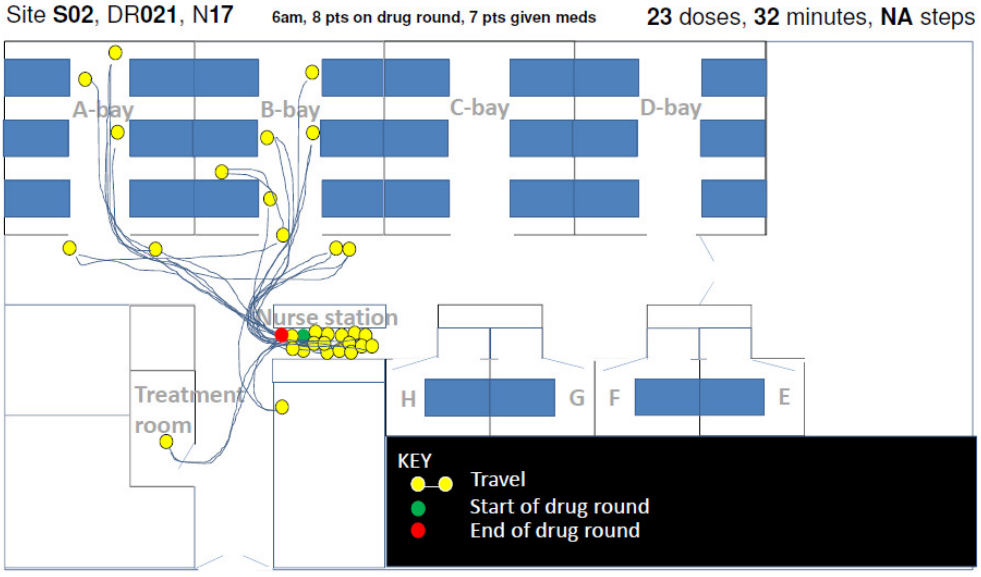


Appendix 30 – Maps of travel by the nurse during drug rounds observed at site B for the medication administration processes and systems (MAPS) study. S02, site 2; DR[number] indicates drug round code; N[number] indicates nurse participant code; NA, not applicable; pts, patients.

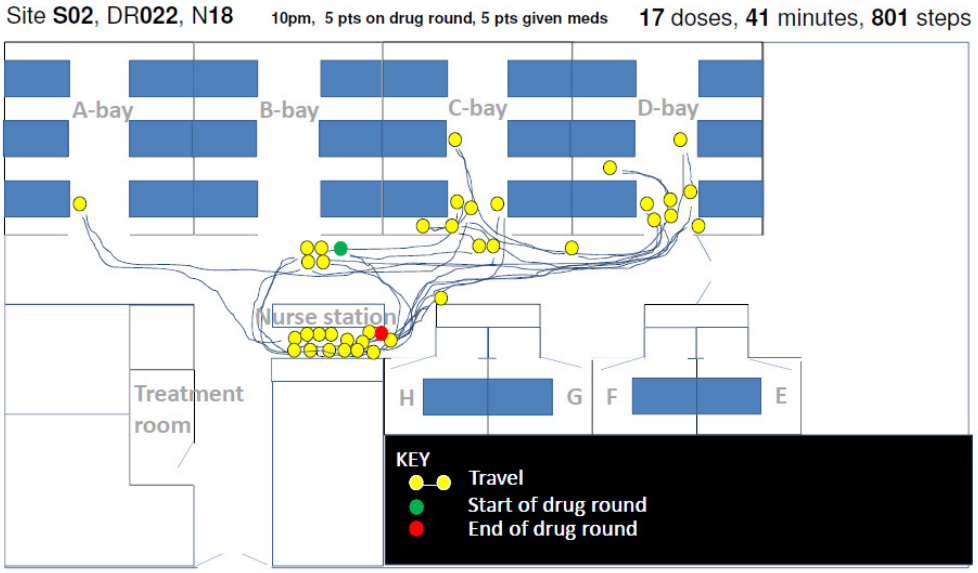


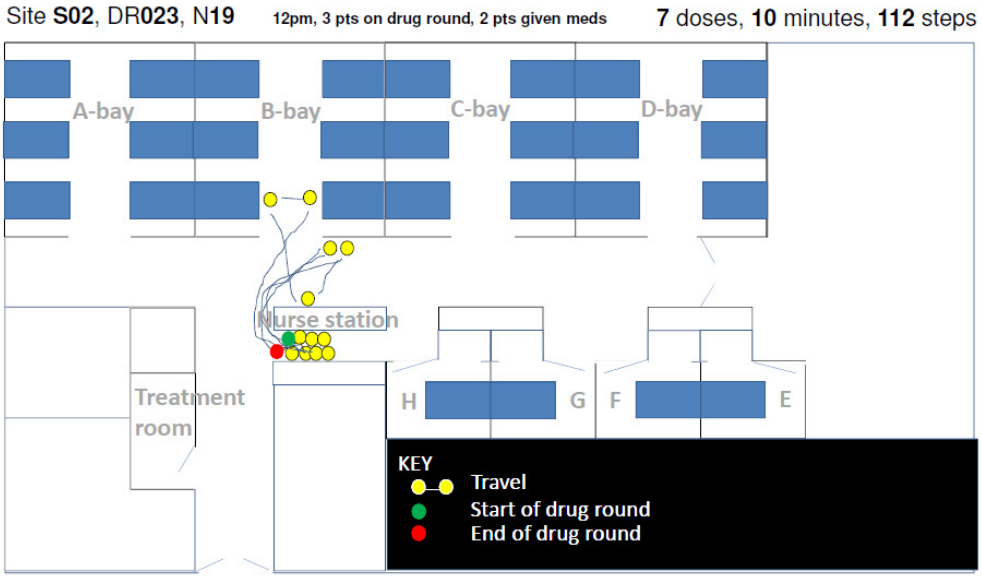
Appendix 30 continued



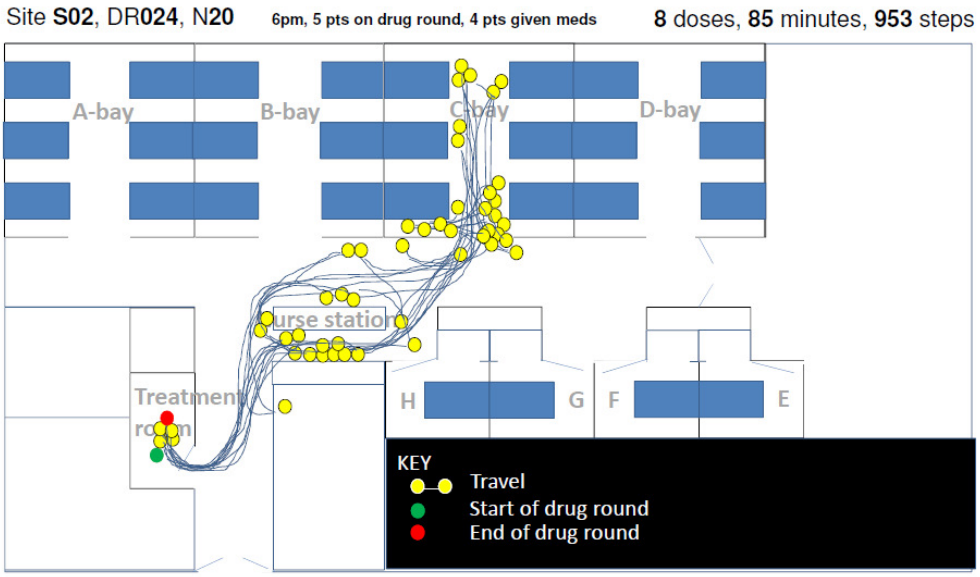


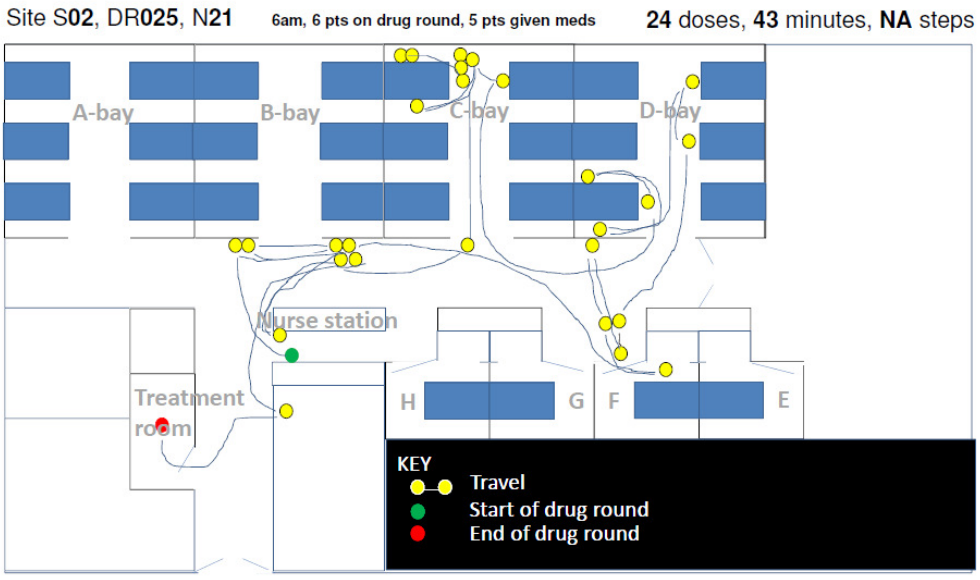
Appendix 30 continued



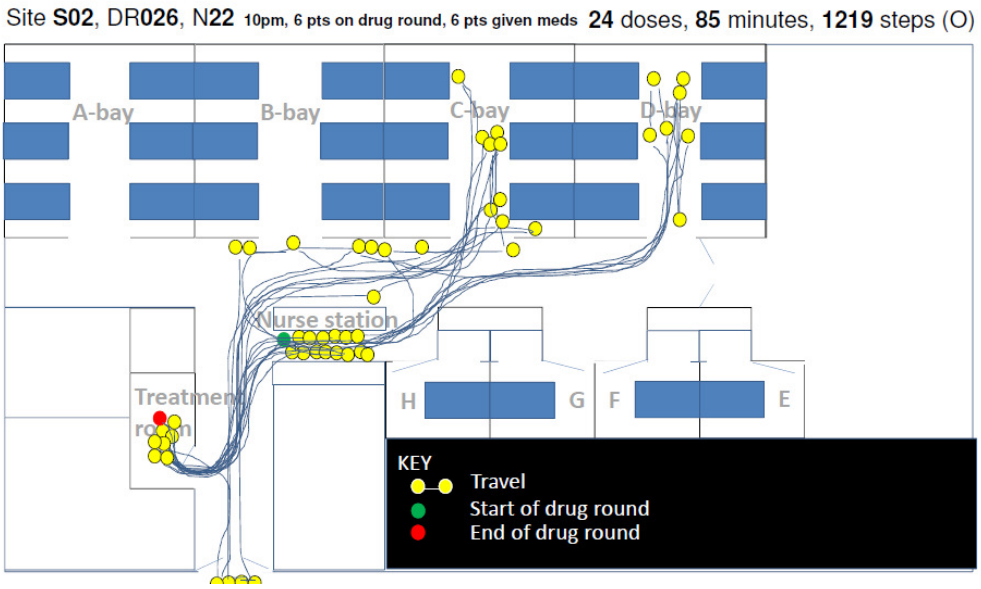


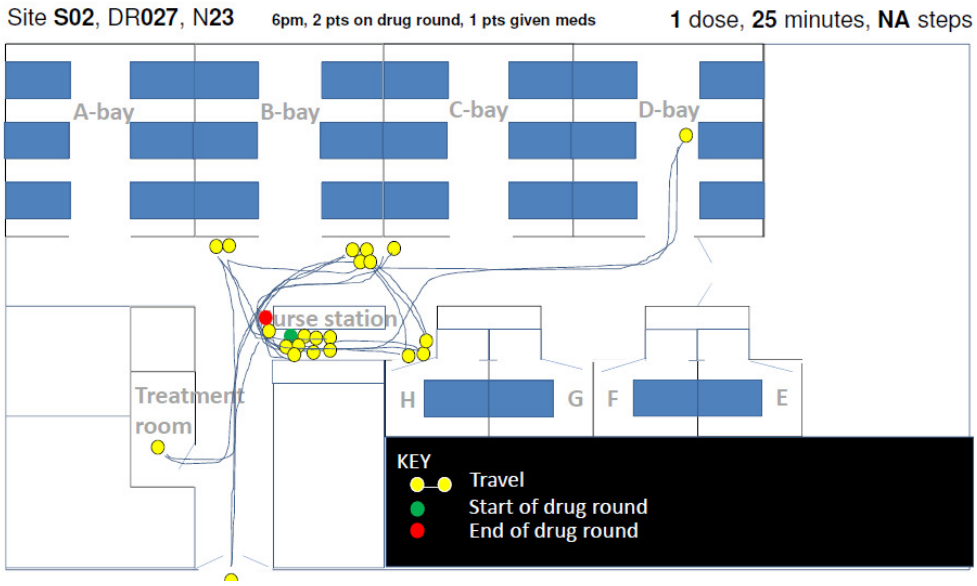
Appendix 30 continued



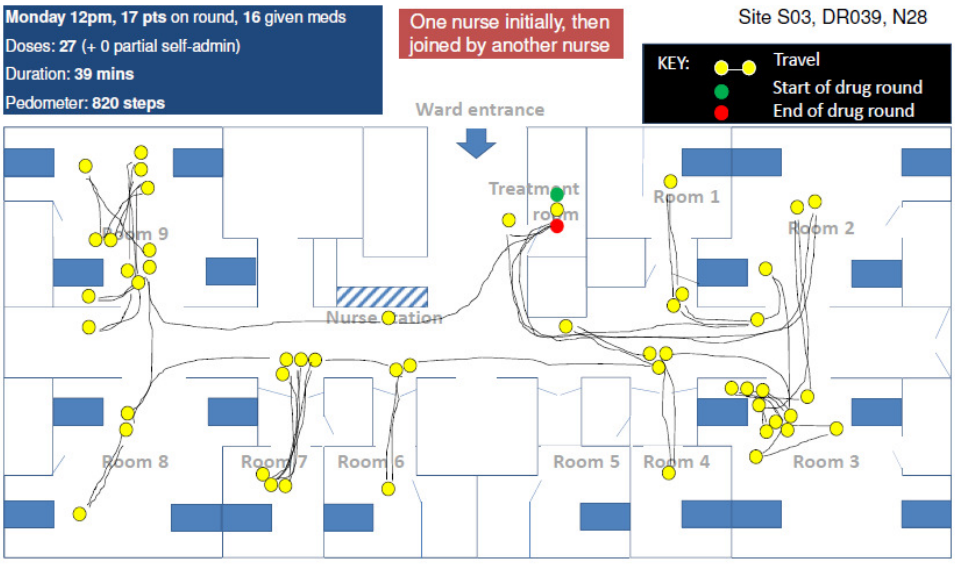


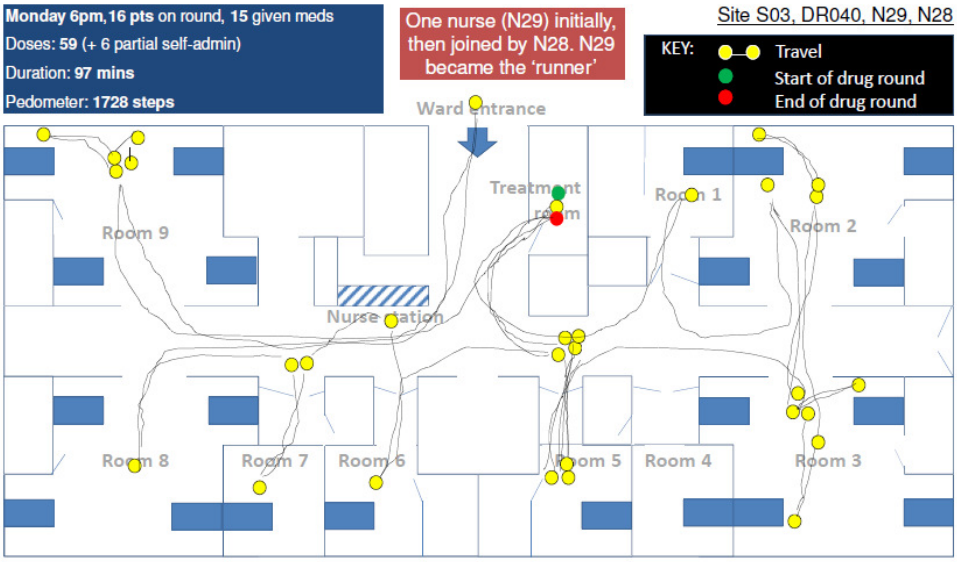
Appendix 30 continued



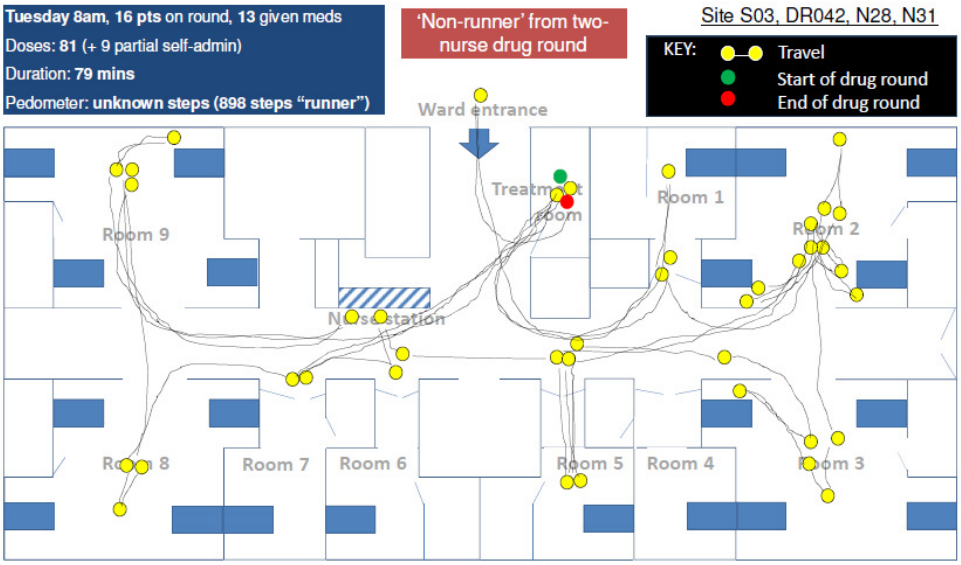


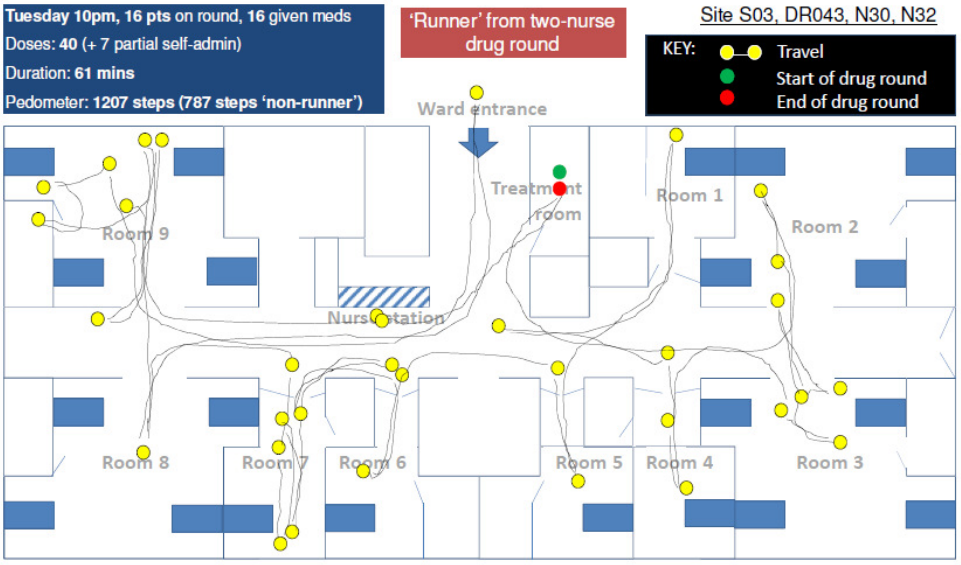
Appendix 31 – Maps of travel by the nurse during drug rounds observed at site C for the medication administration processes and systems (MAPS) study. S02, site 2; DR[number] indicates drug round code; N[number] indicates nurse participant code; NA, not applicable; pts, patients.



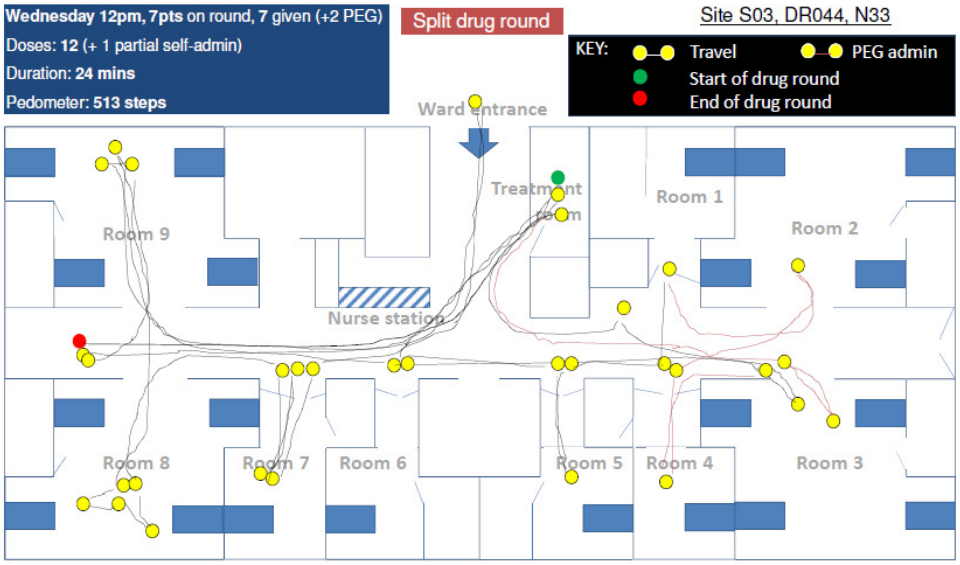


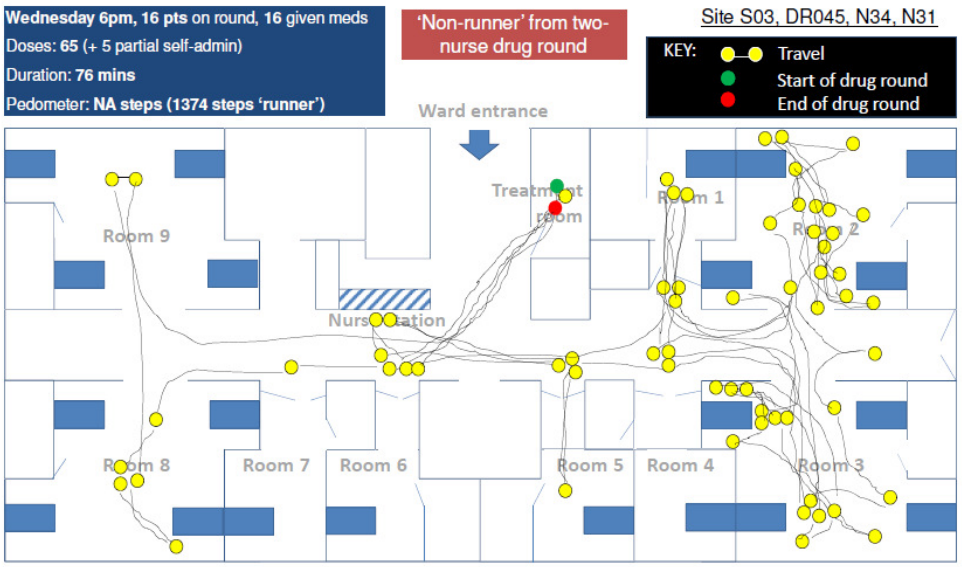
Appendix 31 continued





Appendix 31 continued





Appendix 31 continued